Chemistry Reference Manual

Synchron CX® Clinical Systems

For *In Vitro* Diagnostic Use

This manual is intended for use with
Synchron CX®4/CX®5
Synchron CX4/CX5/CX7/CX9 PRO
Synchron CX4/CX5/CX7 DELTA
Synchron CX4CE/CX5CE/CX7
Synchron CX7 RTS/CX9 ALX

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BECKMAN COULTER®

Chemistry Reference Manual
Synchron CX® Clinical Systems
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Chemistry Reference Manual

What's New for This Release

The Chemistry Information Manual has been separated into the following documents:

- The Chemistry Information Manual contains the individual information sheets for each assay chemistry supported on the SYNCHRON CX. Use this manual for detailed information on specific chemistries. Insert your own laboratory-specific information in the tabbed sections at the end of the manual.
- The Chemistry Reference Manual contains Chemistry Abstracts and other reference information formerly provided at the beginning or end of the Chemistry Information Manual.

Refer to the Beckman Coulter website (www.beckmancoulter.com) for the most recent versions of individual Chemistry Information Sheets.

ADDITIONAL INFORMATION

For more detailed information on SYNCHRON CX PRO Systems, refer to the appropriate SYNCHRON CX manual.

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SYNCHRON CX® PRO Chemistry Information

INTRODUCTION

The SYNCHRON CX PRO System is designed to accommodate serum indices, run on-board sample dilutions for serum, plasma, and urine samples, and enable MANUAL ORDAC functions for immunoproteins.

The SYNCHRON CX PRO System uses Version 6.0 operating software and is identified with a blue stripe on the outside of instrument. If you have a CX PRO System, refer to the blue tabs in your printed Manual for chemistry information. If you are viewing this manual from a CD, refer to the "PRO" bookmarks (table of contents) for chemistry information. The following features apply to all SYNCHRON CX PRO Systems:

SERUM INDICES FEATURE

The Auto Serum Index/ORDAC function permits the enabling or disabling of the Automatic Serum Index function for all samples. When a sample is analyzed for a chemistry, hemolysis, icterus, and lipemia indices are automatically determined. A numeric value (index) for the relative concentration (range) is printed below the Special Calculations area of the patient report. Results for control samples are listed with the test results. The Auto Serum Index is only intended for sample integrity assessment.

ON-BOARD SAMPLE DILUTION FEATURE

Certain cartridge chemistry analyses require the sample to be diluted before analysis. These chemistries include some urine and immunoprotein analyses, or chemistries using the ORDAC function. The SYNCHRON CX PRO system performs these sample dilutions automatically using the DIL1 reagent cartridge. The following chemistries dilutes the sample with DIL1 and dispenses the diluted sample volume into a cuvette:

Type of Analyses	Chemistries Using DIL1
Urine	BUN, MG, PHOS, PO4, UREA, URIC
Immunoprotein	IgA, IgG, IgM, TRF

MANUAL ORDAC

V6.0 software adds MANUAL ORDAC functions to IgA, IgG, IgM and TRF chemistries.

CX PRO SUPPORT DOCUMENTS

In addition to the chemistries noted above, the following documents pertain to SYNCHRON PRO Systems. These documents are also found within the blue tab sections of the CIS manual.

- Serum Index
- DIL1 Reagent
- Chemistry Abstracts
- Calibrators, Controls, and Solutions

SYNCHRON CX PRO Chemistry Abstracts

Table 1.0 SYNCHRON CX PRO Chemistry Abstracts

Chemistry	BUN	IgA	IgG
Methodology	UV-Rate	Immuno-Turbidimetry	Immuno-Turbidimetry
Reaction Type **Analytical Wavelength**	RATE-1 340 nm	EP-2 340 nm	EP-2 340 nm
Sample Type	Serum/Plasma/Urine	Serum	Serum
Sample Volume Serum/Plasma Urine CSF ORDAC	 3 µL 3 µL (1:10 dilution)[a] NA[b] NA	 8 µL (1:26 dilution)[a] NA NA 8 µL (1:101 dilution)[a] MANUAL ORDAC	 4 µL (1:26 dilution)[a] NA NA 4 µL (1:101 dilution)[a] MANUAL ORDAC
Reagent Volume	300 µL	200 µL	200 µL
Cartridge Volume A B C	 285 µL 15 µL NA	 NA 200 µL NA	 NA 200 µL NA
Storage	+2°C to +8°C	+2°C to +8°C	+2°C to +8°C
On-Instrument Stability	30 days	30 days	30 days
Tests/Cartridge **Reagent Volume/Bottle**	300 NA	70 NA	70 NA
Reaction Time Window Start from Sample Addition Stop from Sample Addition	 30 sec. 60 sec.	 500 sec. 560 sec.	 500 sec. 560 sec.
Default Unit	mg/dL	mg/dL	mg/dL
Calibration Frequency	24 hrs	14 days	14 days
Within-lot Calibration Freq.	30 days	NA	NA
Analytical Range Serum Urine CSF	 5 mg/dL to 100 mg/dL 50 mg/dL to 1000 mg/dL NA	 CAL 1 Value to CAL 5 Value NA NA	 CAL 1 Value to CAL 5 Value NA NA
ORDAC Range MIN MAX	 NA NA	 75% × CAL 5 Value 3.9 × CAL 5 Value	 75% × CAL 5 Value 3.9 × CAL 5 Value
Precision Specification (Use the greater number) Serum Urine CSF ORDAC	 2 mg/dL or 3.0% 2 mg/dL or 3.0% NA NA	 10.0 mg/dL or 5.0% NA NA NA	 5.0 mg/dL or 5.0% NA NA NA
Comment	DIL1 required for urine dilution.	DIL1 required for sample dilution.	DIL1 required for sample dilution.

a Reaction volume, actual required sample volume differs due to on-board dilution. Refer to Chemistry Information Sheet for details.

b NA = Not applicable.

Table 2.0 SYNCHRON CX PRO Chemistry Abstracts

Chemistry	IgM	MG	PHOS/PO4
Methodology	Immuno-Turbidimetry	Calmagite	Phospho-Molybdate
Reaction Type **Analytical Wavelength**	EP-2 340 nm	EP-2 520 nm	EP-2 340 nm
Sample Type	Serum	Serum/Plasma/Urine	Serum/Plasma/Urine
Sample Volume Serum/Plasma Urine CSF ORDAC	 20 µL (1:26 dilution)[a] NA[b] NA 20 µL (1:101 dilution)[a] MANUAL ORDAC	 3 µL 3 µL (1:10 dilution)[a] NA NA	 4 µL 4 µL (1:10 dilution)[a] NA NA
Reagent Volume	200 µL	308 µL	267 µL
Cartridge Volume A B C	 NA 200 µL NA	 280 µL 28 µL NA	 243 µL 24 µL NA
Storage	+2°C to +8°C	Room temperature	Room temperature
On-Instrument Stability	30 days	7 days	30 days
Tests/Cartridge **Reagent Volume/Bottle**	70 NA	100 NA	300 NA
Reaction Time Window Start from Sample Addition Stop from Sample Addition	 500 sec. 560 sec.	 64 sec. 96 sec.	 120 sec. 150 sec.
Default Unit	mg/dL	mg/dL	mg/dL
Calibration Frequency	14 days	7 days	14 days
Within-lot Calibration Freq.	NA	90 days	60 days
Analytical Range Serum Urine CSF	 CAL 1 Value to CAL 5 Value NA NA	 0.1 mg/dL to 7.0 mg/dL 1.0 mg/dL to 70.0 mg/dL NA	 1 mg/dL to 12 mg/dL 10 mg/dL to 120 mg/dL NA
ORDAC Range MIN MAX	 75% × CAL 5 Value 3.9 × CAL 5 Value	 NA NA	 NA NA
Precision Specification (Use the greater number) Serum Urine CSF ORDAC	 10.0 mg/dL or 5.0% NA NA 10%	 0.08 mg/dL or 2.0% 0.08 mg/dL or 2.0% NA NA	 0.2 mg/dL or 2.0% 0.2 mg/dL or 2.0% NA NA
Comment	DIL1 required for sample dilution.	DIL1 required for urine dilution.	DIL1 required for urine dilution.

a Reaction volume, actual required sample volume differs due to on-board dilution. Refer to Chemistry Information Sheet for details.

b NA = Not applicable.

Table 3.0 SYNCHRON CX PRO Chemistry Abstracts

Chemistry	TRF	UREA	URIC
Methodology	Immuno-Turbidimetry	UV-Rate	Enzymatic Trinder
Reaction Type **Analytical Wavelength**	EP-2 340 nm	RATE-1 340 nm	EP-2 520 nm
Sample Type	Serum	Serum/Plasma/Urine	Serum/Plasma/Urine
Sample Volume Serum/Plasma Urine CSF ORDAC	 10 µL (1:26 dilution)[a] NA[b] NA 10 µL (1:101 dilution)[a] MANUAL ORDAC	 3 µL 3 µL (1:10 dilution)[a] NA NA	 12 µL 12 µL (1:10 dilution)[a] NA NA
Reagent Volume	200 µL	300 µL	300 µL
Cartridge Volume A B C	 NA 200 µL NA	 285 µL 15 µL NA	 270 µL 30 µL NA
Storage	+2°C to +8°C	+2°C to +8°C	+2°C to +8°C
On-Instrument Stability	30 days	30 days	30 days
Tests/Cartridge **Reagent Volume/Bottle**	70 NA	300 NA	300 NA
Reaction Time Window Start from Sample Addition Stop from Sample Addition	 500 sec. 560 sec.	 30 sec. 60 sec.	 440 sec. 480 sec.
Default Unit	mg/dL	mg/dL	mg/dL
Calibration Frequency	14 days	24 hours	14 days
Within-lot Calibration Freq.	NA	30 days	90 days
Analytical Range Serum Urine CSF	 CAL 1 Value to CAL 5 Value NA NA	 1.8 mmol/L to 35.7 mmol/L 18.0 mmol/L to 357.0 mmol/L NA	 0.5 mg/dL to 12 mg/dL 5.0 mg/dL to 120.0 mg/dL NA
ORDAC Range MIN MAX	 75% × CAL 5 Value 3.9 × CAL 5 Value	 NA NA	 NA NA
Precision Specification (Use the greater number) Serum Urine CSF ORDAC	 5.0 mg/dL or 5.0% NA NA 10%	 0.7 mmol/L or 3.0% 0.7 mmol/L or 3.0% NA NA	 0.15 mg/dL or 2.0% 0.15 mg/dL or 2.0% NA NA
Comment	DIL1 required for sample dilution.	DIL1 required for urine dilution.	DIL1 required for urine dilution.

a Reaction volume, actual required sample volume differs due to on-board dilution. Refer to Chemistry Information Sheet for details.

b NA = Not applicable.

SYNCHRON CX5 ISE Chemistry Abstracts

Table 4.0 SYNCHRON CX5 ISE Chemistry Abstracts

Chemistry	NA	K
Measurement Type	Endpoint	Endpoint
Measurement Principle	Indirect ISE	Indirect ISE
Chemical Principle	LAS glass membrane	Valinomycin membrane
Measurement Time Serum/Plasma CSF Urine	 23 sec. NA[a] 23 sec.	 23 sec. NA 23 sec.
Within-Run Imprecision (Use the greater number) Serum/Plasma CSF Urine	 1% or 1 mmol/L NA 4% or 2 mmol/L	 2% or 0.1 mmol/L NA 4% or 2 mmol/L
Total Imprecision Serum/Plasma CSF Urine	 1.5% or 1.5 mmol/L NA 6% or 3.0 mmol/L	 3% or 0.15 mmol/L NA 6% or 3.0 mmol/L
Analytical Range Serum/Plasma CSF Urine	 100 mmol/L to 200 mmol/L NA 10 mmol/L to 200 mmol/L	 1 mmol/L to 15.0 mmol/L NA 2 mmol/L to 200 mmol/L
Sample Type	Serum/Plasma/Urine	Serum/Plasma/Urine
Sample Size Serum/Plasma CSF Urine	 69 µL[b] NA 69 µL[b]	 69 µL[b] NA 69 µL[b]
Reagent Volume per test (approx.) On-Instrument Stability Storage	 0.81 mL ISE Electrolyte Buffer (IEB)[c] 6.87 mL Deionized Water[c] 1.00 mL ISE Electrolyte Reference (IER)[c] IEB - 60 days IER - 30 days Room temperature	 0.81 mL ISE Electrolyte Buffer (IEB)[c] 6.87 mL Wash Solution[c] 1.00 mL ISE Electrolyte Reference (IER)[c] IEB - 60 days IER - 30 days Room temperature
Temperature Set-point Regulation	 No heater NA	 No heater NA
Calibration DATA (ADC #) Aqueous CAL #1 CAL #2 Minimum Span Back-to-Back CAL # CAL # Frequency	 -170 to 0 +300 to +600 370 15 15 8 hrs.	 -65 to +85 -685 to -485 420 10 10 8 hrs.

a NA = Not applicable.

b 69 µL Sample Total to Complete NA, K, CL, and CO2.

c Total Reagent Volumes to Complete NA, K, CL, CO2, and CALC Analysis.

Table 5.0 SYNCHRON CX5 ISE Chemistry Abstracts

Chemistry	CL	CO_2
Measurement Type	Endpoint	Peak rate
Measurement Principle	Indirect ISE	Differential rate pH
Chemical Principle	Ag/AgCl pellet	Acid liberation CO_2 Gas
Measurement Time		
Serum/Plasma	23 sec.	17.6 sec.
CSF	23 sec.	NA[a]
Urine	23 sec.	NA
Within-Run Imprecision (Use the greater number)		
Serum/Plasma	2% or 2 mmol/L	3% or 1 mmol/L
CSF	2% or 2 mmol/L	NA
Urine	3% or 3 mmol/L	NA
Total Imprecision		
Serum/Plasma	3% or 3.0 mmol/L	4.5 % or 1.5 mmol/L
CSF	3% or 3.0 mmol/L	NA
Urine	4.5% or 4.5 mmol/L	NA
Analytical Range		
Serum/Plasma	50 mmol/L to 200 mmol/L	5 mmol/L to 40 mmol/L
CSF	50 mmol/L to 200 mmol/L	NA
Urine	15 mmol/L to 300 mmol/L	NA
Sample Type	Serum/Plasma/Urine/CSF	Serum/Plasma
Sample Size		
Serum/Plasma	69 µL[b]	69 µL[b]
CSF	69 µL[b]	NA
Urine	69 µL[b]	NA
Reagent		
Volume per test (approx.)	0.81 mL ISE Electrolyte Buffer (IEB)[c] 6.87 mL Deionized Water[c] 1.00 mL ISE Electrolyte Reference (IER)[c]	0.81 mL ISE Electrolyte Buffer (IEB)[c] 6.87 mL Deionized Water[c] 1.00 mL ISE Electrolyte Reference (IER)[c] 0.65 mL Acid Reagent (AR)[c] Alkaline Buffer (AB)
On-Instrument Stability	IEB - 60 days IER - 30 days	IEB - 60 days IER - 30 days AR - 90 days AB - 30 days
Storage	Room temperature	Room temperature
Temperature		
Set-point	No heater	No heater
Regulation	NA	NA
Calibration		
DATA (ADC #)		
Aqueous		
CAL #1	-50 to +70	-1675 to +275
CAL #2	-400 to -150	-1050 to +2580
Minimum Span	190	450
Back-to-Back		
CAL #	12	less than 5%
CAL #	12	less than 5%
Frequency	8 hrs.	8 hrs.

a NA = Not applicable.

b 62 µL Sample Total to Complete NA, K, CL, CO2, and CALC Analysis.

c Total Reagent Volumes to Complete NA, K, CL, CO2, and CALC Analysis.

SYNCHRON CX5 DELTA ISE Chemistry Abstracts

Table 6.0 SYNCHRON CX5 DELTA ISE Chemistry Abstracts

Chemistry	NA	K	CL
Measurement Type	Endpoint	Endpoint	Endpoint
Measurement Principle	Indirect ISE	Indirect ISE	Indirect ISE
Chemical Principle	LAS glass membrane	Valinomycin membrane	Ag/AgCl pellet
Measurement Time Serum/Plasma CSF Urine	 23 sec. NA[a] 23 sec.	 23 sec. NA 23 sec.	 23 sec. 23 sec. 23 sec.
Within-Run Imprecision (Use the greater number) Serum/Plasma CSF Urine	 1% or 1 mmol/L NA 4% or 2 mmol/L	 2% or 0.1 mmol/L NA 4% or 2 mmol/L	 2% or 2 mmol/L 2% or 2 mmol/L 3% or 3 mmol/L
Total Imprecision Serum/Plasma CSF Urine	 1.5% or 1.5 mmol/L NA 6% or 3.0 mmol/L	 3% or 0.15 mmol/L NA 6% or 3.0 mmol/L	 3% or 3.0 mmol/L 3% or 3.0 mmol/L 4.5% or 4.5 mmol/L
Analytical Range Serum/Plasma CSF Urine	 100 mmol/L to 200 mmol/L NA 10 mmol/L to 300 mmol/L	 1 mmol/L to 15.0 mmol/L NA 2 mmol/L to 300 mmol/L	 50 mmol/L to 200 mmol/L 50 mmol/L to 200 mmol/L 15 mmol/L to 400 mmol/L
Sample Type	Serum/Plasma/Urine	Serum/Plasma/Urine	Serum/Plasma/Urine/CSF
Sample Size Serum/Plasma CSF Urine	 62 µL[b] NA 62 µL[b]	 62 µL[b] NA 62 µL[b]	 62 µL[b] 62 µL[b] 62 µL[b]
Reagent Volume per test (approx.) On-Instrument Stability Storage	 0.81 mL ISE Electrolyte Buffer (IEB)[c] 6.87 mL Deionized Water[c] 1.00 mL ISE Electrolyte Reference (IER)[c] IEB - 60 days IER - 30 days Room temperature	 0.81 mL ISE Electrolyte Buffer (IEB)[c] 6.87 mL Deionized Water[c] 1.00 mL ISE Electrolyte Reference (IER)[c] IEB - 60 days IER - 30 days Room temperature	 0.81 mL ISE Electrolyte Buffer (IEB)[c] 6.87 mL Deionized Water[c] 1.00 mL ISE Electrolyte Reference (IER)[c] IEB - 60 days IER - 30 days Room temperature
Temperature Set-point Regulation	 No heater NA	 No heater NA	 No heater NA
Calibration DATA (ADC #) Aqueous CAL #1 CAL #2 CAL #3 Minimum Span Back-to-Back CAL # CAL # Frequency	 +250 to +630 -660 to -100 +770 to +2835 1 to 2 (350) 2 to 3 (1060) 1, 2 (15) 3 (75) 24 hrs.	 -100 to +100 -700 to -485 -3560 to -1900 1 to 2 (420) 2 to 3 (1100) 1, 2, 3 (10) 24 hrs.	 -1185 to -380 +120 to +600 -110 to +110 1 to 2 (450) 2 to 3 (120) 1, 2, 3 (12) 24 hrs.

a NA = Not applicable.

b 62 µL Sample Total to Complete NA, K, CL, and CO2.

c Total Reagent Volumes to Complete NA, K, CL, CO2, and CALC Analysis.

Table 7.0 SYNCHRON CX5 DELTA ISE Chemistry Abstracts

Chemistry	CO_2	CALC
Measurement Type	Peak rate	Endpoint
Measurement Principle	Differential rate pH	Indirect ISE
Chemical Principle	Acid liberation CO_2 Gas	Ca ionophore membrane
Measurement Time		
Serum/Plasma	17.6 sec.	23 sec.
CSF	NA[a]	NA
Urine	NA	23 sec.
Within-Run Imprecision (Use the greater number)		
Serum/Plasma	3% or 1 mmol/L	2% or 0.2 mg/dL
CSF	NA	NA
Urine	NA	2% or 0.2 mg/dL
Total Imprecision		
Serum/Plasma	4.5 % or 1.5 mmol/L	3% or 0.3 mg/dL
CSF	NA	NA
Urine	NA	3% or 0.3 mg/dL
Analytical Range		
Serum/Plasma	5 mmol/L to 50 mmol/L	2 mg/dL to 15.5 mg/dL
CSF	NA	NA
Urine	NA	2 mg/dL to 15.5 mg/dL
Sample Type	Serum/Plasma	Serum/Plasma/Urine
Sample Size		
Serum/Plasma	62 µL[b]	62 µL[b]
CSF	NA	NA
Urine	NA	62 µL[b]
Reagent		
Volume per test (approx.)	0.81 mL ISE Electrolyte Buffer (IEB)[c] 6.87 mL Deionized Water[c] 1.00 mL ISE Electrolyte Reference (IER)[c] 0.65 mL Acid Reagent (AR)[c] Alkaline Buffer (AB)	0.81 mL ISE Electrolyte Buffer (IEB)[c] 6.87 mL Deionized Water[c] 1.00 mL ISE Electrolyte Reference (IER)[c]
On-Instrument Stability	IEB - 60 days IER - 30 days AR - 90 days AB - 30 days	IEB - 60 days IER - 30 days
Storage	Room temperature	Room temperature
Temperature		
Set-point	No heater	No heater
Regulation	NA	NA
Calibration		
DATA (ADC #)		
Aqueous		
CAL #1	-2000 to -100	+60 to +340
CAL #2	NA	-690 to -250
CAL #3	-1000 to +3500	NA
Minimum Span	1 to 3 (450)	1 to 2 (350)
Back-to-Back CAL #	1, 3 (less than 5%)	1, 2 (10)
Frequency	24 hrs.	24 hrs.

a NA = Not applicable.

b 62 µL Sample Total to Complete NA, K, CL, and CO2.

c Total Reagent Volumes to Complete NA, K, CL, CO2, and CALC Analysis.

SYNCHRON CX7 DELTA ISE Chemistry Abstracts

Table 8.0 SYNCHRON CX7 DELTA ISE Chemistry Abstracts

Chemistry	NA	K	CL
Measurement Type	Endpoint	Endpoint	Endpoint
Measurement Principle	Indirect ISE	Indirect ISE	Indirect ISE
Chemical Principle	LAS glass membrane	Valinomycin membrane	Ag/AgCl pellet
Measurement Time Serum/Plasma CSF Urine	 23 sec. NA[a] 23 sec.	 23 sec. NA 23 sec.	 23 sec. 23 sec. 23 sec.
Within-Run Imprecision (Use the greater number) Serum/Plasma CSF Urine	 1% or 1 mmol/L NA 4% or 2 mmol/L	 2% or 0.1 mmol/L NA 4% or 2 mmol/L	 2% or 2 mmol/L 2% or 2 mmol/L 3% or 3 mmol/L
Total Imprecision Serum/Plasma CSF Urine	 1.5% or 1.5 mmol/L NA 6% or 3.0 mmol/L	 3% or 0.15 mmol/L NA 6% or 3.0 mmol/L	 3% or 3.0 mmol/L 3% or 3.0 mmol/L 4.5% or 4.5 mmol/L
Analytical Range Serum/Plasma CSF Urine	 100 mmol/L to 200 mmol/L NA 10 mmol/L to 300 mmol/L	 1 mmol/L to 15.0 mmol/L NA 2 mmol/L to 300 mmol/L	 50 mmol/L to 200 mmol/L 50 mmol/L to 200 mmol/L 15 mmol/L to 400 mmol/L
Sample Type	Serum/Plasma/Urine	Serum/Plasma/Urine	Serum/Plasma/Urine/CSF
Sample Size Serum/Plasma CSF Urine	 62 µL[b] NA 62 µL[b]	 62 µL[b] NA 62 µL[b]	 62 µL[b] 62 µL[b] 62 µL[b]
Reagent Volume per test (approx.) On-Instrument Stability Storage	 0.81 mL ISE Electrolyte Buffer (IEB)[c] 6.87 mL Wash Solution[c] 1.00 mL ISE Electrolyte Reference (IER)[c] IEB - 60 days IER - 30 days Wash - 30 days Room temperature	 0.81 mL ISE Electrolyte Buffer (IEB)[c] 6.87 mL Wash Solution[c] 1.00 mL ISE Electrolyte Reference (IER)[c] IEB - 60 days IER - 30 days Wash - 30 days Room temperature	 0.81 mL ISE Electrolyte Buffer (IEB)[c] 6.87 mL Wash Solution[c] 1.00 mL ISE Electrolyte Reference (IER)[c] IEB - 60 days IER - 30 days Wash - 30 days Room temperature
Temperature Set-point Regulation	 No heater NA	 No heater NA	 No heater NA
Calibration DATA (ADC #) Aqueous CAL #1 CAL #2 CAL #3 Minimum Span CAL # CAL # Back-to-Back CAL # CAL # Frequency	 +250 to +630 -660 to -100 +770 to +2835 1 to 2 (350) 2 to 3 (1060) 1, 2 (15) 3 (75) 24 hrs.	 -100 to +100 -700 to -485 -3560 to -1900 1 to 2 (420) 2 to 3 (1100) 1, 2, 3 (10) 24 hrs.	 -1185 to -380 +120 to +600 -110 to +110 1 to 2 (450) 2 to 3 (120) 1, 2, 3 (12) 24 hrs.

a NA = Not applicable.

b 62 µL Sample Total to Complete NA, K, CL, CO2, and CALC Analysis.

c Total Reagent Volumes to Complete NA, K, CL, CO2, and CALC Analysis.

Table 9.0 SYNCHRON CX7 DELTA ISE Chemistry Abstracts

Chemistry	CO_2	CALC
Measurement Type	Peak rate	Endpoint
Measurement Principle	Differential rate pH	Indirect ISE
Chemical Principle	Acid liberation CO_2 Gas	Ca ionophore membrane
Measurement Time Serum/Plasma CSF Urine	 17.6 sec. NA[a] NA	 23 sec. NA 23 sec.
Within-Run Imprecision (Use the greater number) Serum/Plasma CSF Urine	 3% or 1 mmol/L NA NA	 2% or 0.2 mg/dL NA 2% or 0.2 mg/dL
Total Imprecision Serum/Plasma CSF Urine	 4.5 % or 1.5 mmol/L NA NA	 3% or 0.3 mg/dL NA 3% or 0.3 mg/dL
Analytical Range Serum/Plasma CSF Urine	 5 mmol/L to 50 mmol/L NA NA	 2 mg/dL to 15.5 mg/dL NA 2 mg/dL to 15.5 mg/dL
Sample Type	Serum/Plasma	Serum/Plasma/Urine
Sample Size Serum/Plasma CSF Urine	 62 µL[b] NA NA	 62 µL[b] NA 62 µL[b]
Reagent Volume per test (approx.) On-Instrument Stability Storage	 0.81 mL ISE Electrolyte Buffer (IEB)[c] 6.87 mL Wash Solution[c] 1.00 mL ISE Electrolyte Reference (IER)[c] 0.65 mL Acid Reagent (AR)[c] Alkaline Buffer (AB) IEB - 60 days IER - 30 days AR - 90 days AB - 30 days Wash - 30 days Room temperature	 0.81 mL ISE Electrolyte Buffer (IEB)[c] 6.87 mL Wash Solution[c] 1.00 mL ISE Electrolyte Reference (IER)[c] IEB - 60 days IER - 30 days Wash - 30 days Room temperature
Temperature Set-point Regulation	 No heater NA	 No heater NA
Calibration DATA (ADC #) Aqueous CAL #1 CAL #2 CAL #3 Minimum Span CAL # Back-to-Back CAL # Frequency	 -2000 to -100 NA -1000 to +3500 1 to 3 (450) 1, 3 (less than 5%) 24 hrs.	 +60 to +340 -690 to -250 NA 1 to 2 (350) 1, 2 (10) 24 hrs.

a NA = Not applicable.

b 62 µL Sample Total to Complete NA, K, CL, CO2, and CALC Analysis.

c Total Reagent Volumes to Complete NA, K, CL, CO2, and CALC Analysis.

SYNCHRON CX7 DELTA CUP Chemistry Abstracts

Table 10.0 SYNCHRON CX7 DELTA CUP Chemistry Abstracts

Chemistry	BUN3	URE3	GLU3
Measurement Type	Timed rate	Timed rate	Timed-peak rate
Measurement Principle	Conductivity	Conductivity	O_2 depletion
Chemical Principle	Urease (liquid)	Urease (liquid)	Glucose oxidase
Measurement Time			
Serum/Plasma	11.5 sec.	11.5 sec.	9.6 sec.
CSF	NA[a]	NA	9.6 sec.
Urine	11.5 sec.	11.5 sec.	9.6 sec.
ORDAC	11.5 sec.	11.5 sec.	9.6 sec.
Within-Run Imprecision (Use the greater number)			
Serum/Plasma	3% or 1.5 mg/dL	3% or 0.5 mmol/L	2% or 2 mg/dL
CSF	NA	NA	2% or 2 mg/dL
Urine	5% or 1.5 mg/dL	5% or 1.0 mmol/L	2% or 2 mg/dL
ORDAC	5%	5%	5%
Total Imprecision			
Serum/Plasma	4.5% or 2.3 mg/dL	4.5% or 0.8 mmol/L	3% or 3 mg/dL
CSF	NA	NA	3% or 3 mg/dL
Urine	7.5% or 3.8 mg/dL	7.5% or 1.5 mmol/L	3% or 3 mg/dL
ORDAC	7.5%	7.5%	7.5%
Analytical Range			
Serum/Plasma	0 mg/dL to 150 mg/dL	0 mmol/L to 53.6 mmol/L	0 mg/dL to 450 mg/dL
CSF	NA	NA	0 mg/dL to 450 mg/dL
Urine	0 mg/dL to 150 mg/dL	0 mmol/L to 53.6 mmol/L	0 mg/dL to 450 mg/dL
ORDAC	150 mg/dL to 300 mg/dL	53.6 mmol/L to 107.2 mmol/L	450 mg/dL to 900 mg/dL
Sample Type	Serum/Plasma/Urine	Serum/Plasma/Urine	Serum/Plasma/Urine/CSF
Sample Size			
Serum/Plasma	10 µL	10 µL	10 µL
CSF	NA	NA	10 µL
Urine	10 µL	10 µL	10 µL
ORDAC	5 µL	5 µL	5 µL
Reagent			
Volume per test (approx.)	0.22 mL Urease 0.88 mL Wash Solution	0.22 mL Urease 0.88 mL Wash Solution	0.22 mL Glucose oxidase 0.88 mL Wash Solution
On-Instrument Stability	Urease - 30 days Wash - 30 days	Urease - 30 days Wash - 30 days	Glucose oxidase - 30 days Wash - 30 days
Storage	+2°C to +8°C	+2°C to +8°C	+2°C to +8°C
Temperature			
Set-point	+36°C to +38°C	+36°C to +38°C	+36°C to +38°C
Regulation	±0.2°C	±0.2°C	±0.2°C
Stirrer			
Size	Small (white)	Small (white)	Small (white)
Speed (RPM)	720	720	900
Calibration			
DATA (ADC #)			
Aqueous			
CAL #1	-250 to -65	-250 to -65	+1060 to +1650
CAL #2	-1900 to -750	-1900 to -750	+250 to +560
CAL #3	NA	NA	NA
Minimum Span	1 to 2 (700)	1 to 2 (700)	1 to 2 (750)
Back-to-Back CAL #	1,2 (20)	1,2 (20)	1,2 (24)
Frequency	24 hrs.	24 hrs.	24 hrs.

a NA = Not applicable.

Table 11.0 SYNCHRON CX7 DELTA CUP Chemistry Abstracts

Chemistry	CRE3	CA3	TP3
Measurement Type	Timed rate	Endpoint	Timed rate
Measurement Principle	Colorimetry (520 nm, 560 nm)	Colorimetry (650 nm, 700 nm)	Colorimetry (545 nm)
Chemical Principle	Alkaline picrate	Arsenazo III	Biuret
Measurement Time Serum/Plasma CSF Urine ORDAC	 25.6 sec. NA 25.6 sec. NA	 21 sec. NA[a] 21 sec. NA	 11 sec. 17.5 sec. NA NA
Within-Run Imprecision (Use the greater number) Serum/Plasma CSF Urine ORDAC	 3% or 0.1 mg/dL NA 3% or 2 mg/dL NA	 2% or 0.2 mg/dL NA 2% or 0.2 mg/dL NA	 2% or 0.2 g/dL 5% or 50 mg/dL NA NA
Total Imprecision Serum/Plasma CSF Urine ORDAC	 4.5% or 0.2 mg/dL NA 4.5% or 3.0 mg/dL NA	 3% or 0.3 mg/dL NA 3% or 0.3 mg/dL NA	 3% or 0.3 g/dL 7.5 % or 75 mg/dL NA NA
Analytical Range Serum/Plasma CSF Urine ORDAC	 0 mg/dL to 25 mg/dL NA 10 mg/dL to 400 mg/dL NA	 0 mg/dL to 15.5 mg/dL NA 0 mg/dL to 15.5 mg/dL NA	 3 g/dL to 12.0 g/dL 10 mg/dL to 750 mg/dL NA NA
Sample Type	Serum/Plasma/Urine	Serum/Plasma/Urine	Serum/Plasma/CSF
Sample Size Serum/Plasma CSF Urine ORDAC	 30 µL NA 10 µL NA	 10 µL NA 10 µL NA	 10 µL 80 µL NA NA
Reagent Volume per test On-Instrument Stability Storage	 1.25 mL 30 days Room temperature	 1.25 mL 60 days Room temperature	 1.25 mL 60 days Room temperature
Temperature Set-point Regulation	 +40°C to +42°C ±0.2°C	 +36°C to +38°C ±0.2°C	 +36°C to +38°C ±0.2°C
Stirrer Size Speed (RPM)	 Large (blue) 720	 Large (blue) 720	 Large (blue) 900
Calibration DATA (ADC #) Aqueous CAL #1 CAL #2 CAL #3 Minimum Span Back-to-Back CAL # Frequency	 -140 to -40 -920 to -500 NA 1 to 2 (390) 1,2 (16) 24 hrs.	 -310 to -180 -870 to -530 NA 1 to 2 (360) 1,2 (10) 24 hrs.	 Calibration data may vary with calibrator lot. 24 hrs.

a NA = Not applicable.

SYNCHRON CX Systems Chemistry Abstracts

Table 12.0 SYNCHRON CX Systems Chemistry Abstracts

Chemistry	ACTM	ALB	ALP
Methodology	Immuno-Turbidimetry	BCP	AACC
Reaction Type[a] **Analytical Wavelength**	RATE-1 340 nm	EP-2 600 nm	RATE-1 410 nm
Sample Type	Serum/Plasma	Serum/Plasma	Serum/Plasma
Sample Volume Serum/Plasma Urine CSF ORDAC	 5 µL NA[b] NA NA	 3 µL NA NA NA	 5 µL NA NA 3 µL
Reagent Volume	302 µL	300 µL	250 µL
Cartridge Volume A B C	 230 µL 40 µL 32 µL	 300 µL NA NA	 228 µL 22 µL NA
Storage	+2°C to +8°C	Room temperature	+2°C to +8°C
On-Instrument Stability	42 days	30 days	10 days
Tests per Cartridge	100	300	200 or 400
Reaction Time Window Start from Sample Addition Stop from Sample Addition	 112 sec. 160 sec.	 75 sec. 105 sec.	 130 sec. 280 sec.
Default Unit	µg/mL	g/dL	IU/L
Calibration Frequency	7 days	14 days	NA
Within-lot Cal. Frequency	60 days	90 days	NA
Analytical Range Serum Urine CSF	 10 µg/mL to 300 µg/mL NA NA	 1 g/dL to 7 g/dL NA NA	 5 IU/L to 1000 IU/L NA NA
ORDAC Range	NA	NA	800 IU/L to 1800 IU/L
Precision Specification (Use the greater number) Serum Urine CSF ORDAC	 2.0 µg/mL or 4.0% NA NA NA	 0.2 g/dL or 3.0% NA NA NA	 3.0 IU/L or 3.5% NA NA 10%
Comment	Run at 37°C only.	NA	NA

a 1 = Reagent blank not subtracted during calculation of result. 2 = Reagent blank subtracted during calculation of result.

b NA = Not applicable.

Table 13.0 SYNCHRON CX Systems Chemistry Abstracts

Chemistry	ALPd	ALT	ALT-
Methodology	DGKC	Henry	P5P activated
Reaction Type[a] **Analytical Wavelength**	RATE-1 410 nm	RATE-1 340 nm	RATE-1 340 nm
Sample Type	Serum/Plasma	Serum/Plasma	Serum/Plasma
Sample Volume Serum/Plasma Urine CSF ORDAC	 5 µL NA[b] NA 3 µL	 23 µL NA NA 3 µL	 23 µL NA NA 3 µL
Reagent Volume	250 µL	250 µL	258 µL
Cartridge Volume A B C	 250 µL NA NA	 242 µL 8 µL NA	 250 µL 8 µL NA
Storage	+2°C to +8°C	+2°C to +8°C	+2°C to +8°C
On-Instrument Stability	3 days	30 days	5 days
Tests per Cartridge	150	200 or 400	100/300
Reaction Time Window Start from Sample Addition Stop from Sample Addition	 60 sec. 180 sec.	 112 sec. 176 sec.	 2242 sec. 304 sec.
Default Unit	IU/L	IU/L	IU/L
Calibration Frequency	NA	NA	5 days
Within-lot Cal. Frequency	NA	NA	NA
Analytical Range Serum Urine CSF	 10 U/L to 1000 U/L NA NA	 5 IU/L to 400 IU/L NA NA	 5 IU/L to 400 IU/L NA NA
ORDAC Range	750 U/L to 1650 U/L	350 IU/L to 2600 IU/L	350 IU/L to 2600 IU/L
Precision Specification (Use the greater number) Serum Urine CSF ORDAC	 3 U/L or 3.5% NA NA 10%	 3.0 IU/L or 3.5% NA NA 10%	 3.0 IU/L or 3.5% NA NA 10%
Comment	NA	Mix C into A (for 200 tests). Mix ALT (A-reagent) into A (for 400 tests).	Run at 37°C only, Mix C into A.

a 1 = Reagent blank not subtracted during calculation of result. 2 = Reagent blank subtracted during calculation of result.

b NA = Not applicable.

Table 14.0 SYNCHRON CX Systems Chemistry Abstracts

Chemistry	AMM	AMPH	AMY
Methodology	Enzymatic	EIA	Enzymatic-DS
Reaction Type[a] **Analytical Wavelength**	EP-2 340 nm	RATE-1 340 nm	RATE-1 340 nm
Sample Type	Plasma	Urine	Serum/Plasma/Urine
Sample Volume Serum/Plasma Urine CSF ORDAC	 25 µL NA[b] NA NA	 NA 20 µL NA NA	 12 µL 12 µL NA 3 µL
Reagent Volume	226 µL	250 µL	250 µL
Cartridge Volume A B C	 180 µL 40 µL 6 µL	 200 µL 50 µL NA	 238 µL NA 12 µL
Storage	+2°C to +8°C	+2°C to +8°C	+2°C to +8°C
On-Instrument Stability	30 days	90 days	30 days
Tests per Cartridge	25	250	200
Reaction Time Window Start from Sample Addition Stop from Sample Addition	 300 sec. 350 sec.	 96 sec. 144 sec.	 200 sec. 260 sec.
Default Unit	µmol/L	mAbs/min	U/L
Calibration Frequency	5 days	14 days	NA
Within-lot Cal. Frequency	NA	90 days	NA
Analytical Range Serum Urine CSF	 9 µmol/L to 1000 µmol/L[c] NA NA	 NA NA NA	 5 U/L to 800 U/L 5 U/L to 800 U/L NA
ORDAC Range	NA	NA	600 U/L to 2400 U/L
Precision Specification (Use the greater number) Serum Urine CSF ORDAC	 5 µmol/L[c] or 2.0% NA NA NA	 NA 2.0% NA NA	 3.0 U/L or 3.5% 3.0 U/L or 3.5% NA 10%
Comment	Run at 37°C only.	Qualitative, POS/NEG Run at 37°C only.	NA

a 1 = Reagent blank not subtracted during calculation of result. 2 = Reagent blank subtracted during calculation of result.
b NA = Not applicable.
c Plasma values.

Table 15.0 SYNCHRON CX Systems Chemistry Abstracts

Chemistry	ASO-	AST	AST-
Methodology	Immuno-Turbidimetry	Henry	P5P activated
Reaction Type[a] **Analytical Wavelength**	RATE-1 340 nm	RATE-1 340 nm	RATE-1 340 nm
Sample Type	Serum/Plasma	Serum/Plasma	Serum/Plasma
Sample Volume Serum/Plasma Urine CSF ORDAC	 6 µL NA[b] NA 3 µL	 23 µL NA NA 3 µL	 23 µL NA NA 3 µL
Reagent Volume	300 µL	250 µL	258 µL
Cartridge Volume A B C	 250 µL 50 µL NA	 242 µL 8 µL NA	 250 µL 8 µL NA
Storage	+2°C to +8°C	+2°C to +8°C	+2°C to +8°C
On-Instrument Stability	60 days	30 days	5 days
Tests per Cartridge	100	200 or 400	100/300
Reaction Time Window Start from Sample Addition Stop from Sample Addition	 10 sec. 40 sec.	 112 sec. 176 sec.	 224 sec. 304 sec.
Default Unit	IU/mL	IU/L	IU/L
Calibration Frequency	30 days	NA	5 days
Within-lot Cal. Frequency	60 days	NA	NA
Analytical Range Serum Urine CSF	 25 IU/mL to 800 IU/mL NA NA	 5 IU/L to 400 IU/L NA NA	 5 IU/L to 400 IU/L NA NA
ORDAC Range	640 IU/mL to 1600 IU/mL	350 IU/L to 2600 IU/L	350 IU/L to 2600 IU/L
Precision Specification (Use the greater number) Serum Urine CSF ORDAC	 10 IU/mL or 4.0% NA NA 4.0%	 3.0 IU/L or 3.5% NA NA 10%	 3 IU/L or 3.5% NA NA 10%
Comment	Run at 37°C only.	Mix C into A (for 200 tests). Mix AST (A-reagent) into A (for 400 tests).	Run at 37°C only, Mix C into A.

a 1 = Reagent blank not subtracted during calculation of result. 2 = Reagent blank subtracted during calculation of result.

b NA = Not applicable.

Table 16.0 SYNCHRON CX Systems Chemistry Abstracts

Chemistry	BARB	BENZ	BNZG
Methodology	EIA	EIA	EIA
Reaction Type[a] **Analytical Wavelength**	RATE-1 340 nm	RATE-1 340 nm	RATE-1 340 nm
Sample Type	Urine	Urine	Urine
Sample Volume Serum/Plasma Urine CSF ORDAC	 NA[b] 10 µL NA NA	 NA[b] 20 µL NA NA	 NA 20 µL NA NA
Reagent Volume	250 µL	250 µL	260 µL
Cartridge Volume A B C	 200 µL 50 µL NA	 200 µL 50 µL NA	 200 µL 50 µL 10 µL
Storage	+2°C to +8°C	+2°C to +8°C	+2°C to +8°C
On-Instrument Stability	90 days	90 days	60 days
Tests per Cartridge	250	250	250
Reaction Time Window Start from Sample Addition Stop from Sample Addition	 96 sec. 144 sec.	 96 sec. 144 sec.	 96 sec. 144 sec.
Default Unit	mAbs/min	mAbs/min	mAbs/min
Calibration Frequency	14 days	14 days	14 days
Within-lot Cal. Frequency	90 days	90 days	60 days
Analytical Range Serum Urine CSF	 NA NA NA	 NA NA NA	 NA NA NA
ORDAC Range	NA	NA	NA
Precision Specification (Use the greater number) Serum Urine CSF ORDAC	 NA 2.0% NA NA	 NA 2.0% NA NA	 NA 3.0% NA NA
Comment	Qualitative, POS/NEG Run at 37°C only.	Qualitative, POS/NEG Run at 37°C only.	Qualitative, POS/NEG Run at 37°C only.

a 1 = Reagent blank not subtracted during calculation of result. 2 = Reagent blank subtracted during calculation of result.

b NA = Not applicable.

b NA = Not applicable.

Table 17.0 SYNCHRON CX Systems Chemistry Abstracts

Chemistry	BUN	CA	CAR
Methodology	UV-Rate	Arsenazo III	Immuno-Turbidimetry
Reaction Type[a] **Analytical Wavelength**	RATE-1 340 nm	EP-2 650 nm	EP-2 340 nm
Sample Type	Serum/Plasma/Urine	Serum/Plasma/Urine	Serum/Plasma
Sample Volume Serum/Plasma Urine CSF ORDAC	 3 µL 3 µL NA[b] NA	 3 µL 3 µL NA NA	 3 µL NA NA NA
Reagent Volume	300 µL	300 µL	292 µL
Cartridge Volume A B C	 285 µL 15 µL NA	 300 µL NA NA	 230 µL 30 µL 32 µL
Storage	+2°C to +8°C	Room temperature	+2°C to +8°C
On-Instrument Stability	30 days	30 days	42 days
Tests per Cartridge	300	300	100
Reaction Time Window Start from Sample Addition Stop from Sample Addition	 30 sec. 60 sec.	 70 sec. 100 sec.	 530 sec. 580 sec.
Default Unit	mg/dL	mg/dL	µg/mL
Calibration Frequency	24 hrs	14 days	14 days
Within-lot Cal. Frequency	30 days	30 days	60 days
Analytical Range Serum Urine CSF	 5 mg/dL to 100 mg/dL 5 mg/dL to 100 mg/dL NA	 2 mg/dL to 15 mg/dL 2 mg/dL to 15 mg/dL NA	 2.0 µg/mL to 20.0 µg/mL NA NA
ORDAC Range	NA	NA	NA
Precision Specification (Use the greater number) Serum Urine CSF ORDAC	 2 mg/dL or 3.0% 2 mg/dL or 3.0% NA NA	 0.2 mg/dL or 2.0% 0.2 mg/dL or 2.0% NA NA	 0.6 µg/mL or 5.0% NA NA NA
Comment	Urine Samples require a 1:10 dilution.	NA	Run at 37°C only.

a 1 = Reagent blank not subtracted during calculation of result. 2 = Reagent blank subtracted during calculation of result.

b NA = Not applicable.

Table 18.0 SYNCHRON CX Systems Chemistry Abstracts

Chemistry	CHE	CHOL	CK
Methodology	S-Butyrylthio-choline iodide	Enzymatic	Rosalki
Reaction Type[a] **Analytical Wavelength**	RATE-1 410 nm	EP-2 520 nm	RATE-1 340 nm
Sample Type	Serum/Plasma	Serum/Plasma	Serum/Plasma
Sample Volume Serum/Plasma Urine CSF ORDAC	 3 µL NA[b] NA NA	 3 µL NA NA NA	 13 µL NA NA 3 µL
Reagent Volume	315 µL	300 µL	260 µL
Cartridge Volume A B C	 300 µL 15 µL NA	 290 µL NA 10 µL	 238 µL 22 µL NA
Storage	+2°C to +8°C	+2°C to +8°C	+2°C to +8°C
On-Instrument Stability	42 days	30 days	30 days
Tests per Cartridge	250	300	200 or 400
Reaction Time Window Start from Sample Addition Stop from Sample Addition	 16 sec. 60 sec.	 320 sec. 352 sec.	 180 sec. 240 sec.
Default Unit	U/L	mg/dL	IU/L
Calibration Frequency	NA	14 days	NA
Within-lot Cal. Frequency	NA	90 days	NA
Analytical Range Serum Urine CSF	 250 U/L to 20,000 U/L NA NA	 5 mg/dL to 750 mg/dL NA NA	 5 IU/L to 1200 IU/L NA NA
ORDAC Range	NA	NA	860 IU/L to 4100 IU/L
Precision Specification (Use the greater number) Serum Urine CSF ORDAC	 60 U/L or 3.5% NA NA NA	 5.0 mg/dL or 3.0% NA NA NA	 5.0 IU/L or 3.5% NA NA 10%
Comment	NA	Run at 37°C only.	Mix C into A (for 200 tests). Mix CK (A-reagent) into A (for 400 tests).

a 1 = Reagent blank not subtracted during calculation of result. 2 = Reagent blank subtracted during calculation of result.

b NA = Not applicable.

Table 19.0 SYNCHRON CX Systems Chemistry Abstracts

Chemistry	CK-	CKMB	CKNa
Methodology	NAC activate ECCLS activated	Immuno-Inhibition	DGKC
Reaction Type[a] **Analytical Wavelength**	RATE-1 340 nm	RATE-2 340 nm	RATE-1 340 nm
Sample Type	Serum/Plasma	Serum/Plasma	Serum/Plasma
Sample Volume Serum/Plasma Urine CSF ORDAC	 12 µL NA[b] NA 3 µL	 24 µL NA NA 12 µL	 10 µL NA NA 3 µL
Reagent Volume	264 µL	252 µL	260 µL
Cartridge Volume A B C	 242 µL 22 µL NA	 NA 240 µL 12 µL	 250 µL NA 10 µL
Storage	+2°C to +8°C	+2°C to +8°C	+2°C to +8°C
On-Instrument Stability	21 days	5 days	7 days
Tests per Cartridge	200	60	200
Reaction Time Window Start from Sample Addition Stop from Sample Addition	 150 sec. 210 sec.	 510 sec. 650 sec.	 300 sec. 420 sec.
Default Unit	IU/L	U/L	U/L
Calibration Frequency	21 days	NA	NA
Within-lot Cal. Frequency	NA	NA	NA
Analytical Range Serum Urine CSF	 5 IU/L to 1200 IU/L NA NA	 0.5 U/L to 150 U/L NA NA	 6 U/L to 1200 U/L NA NA
ORDAC Range	860 IU/L to 4100 IU/L	115 U/L to 300 U/L	900 U/L to 3900 U/L
Precision Specification (Use the greater number) Serum Urine CSF ORDAC	 5.0 IU/L or 3.5% NA NA 10%	 2.0 U/L or 3.5% NA NA 10%	 5 U/L or 3.5% NA NA 10%
Comment	Run at 37°C only. Mix C into A.	NA	NA

a 1 = Reagent blank not subtracted during calculation of result. 2 = Reagent blank subtracted during calculation of result.

b NA = Not applicable.

Table 20.0 SYNCHRON CX Systems Chemistry Abstracts

Chemistry	COCM	CREA	CRP
Methodology	EIA	Rate-Jaffe	Immuno-Turbidimetry
Reaction Type[a] **Analytical Wavelength**	RATE-1 340 nm	RATE-2 520 nm	EP-2 340 nm
Sample Type	Urine	Serum/Plasma/Urine	Serum
Sample Volume Serum/Plasma Urine CSF ORDAC	 NA[b] 20 µL NA NA	 20 µL 3 µL NA NA	 10 µL NA NA 4 µL (Manual ORDAC)
Reagent Volume	250 µL	219 µL	260 µL
Cartridge Volume A B C	 200 µL 50 µL NA	 175 µL 44 µL NA	 250 µL NA 10 µL
Storage	+2°C to +8°C	Room temperature	+2°C to +8°C
On-Instrument Stability	90 days	20 days	60 days
Tests per Cartridge	250	300	200
Reaction Time Window Start from Sample Addition Stop from Sample Addition	 48 sec. 96 sec.	 16 sec. 64 sec.	 560 sec. 592 sec.
Default Unit	mAbs/min	mg/dL	mg/dL
Calibration Frequency	14 days	7 days	30 days
Within-lot Cal. Frequency	90 days	30 days	60 days
Analytical Range Serum Urine CSF	 NA NA NA	 0.3 mg/dL to 25 mg/dL 10 mg/dL to 400 mg/dL NA	 CAL 1 Value to CAL 5 Value NA NA
ORDAC Range	NA	NA	14 mg/dL to 2.5 × CAL 5 Value
Precision Specification (Use the greater number) Serum Urine CSF ORDAC	 NA 2.0% NA NA	 0.2 mg/dL or 3.0% 2.0 mg/dL or 3.0% NA NA	 0.2 mg/dL or 5.0% NA NA NA
Comment	Qualitative, POS/NEG Run at 37°C only.	Add 1 drop of antifoam to compartment A.	NA

a 1 = Reagent blank not subtracted during calculation of result. 2 = Reagent blank subtracted during calculation of result.

b NA = Not applicable.

Table 21.0 SYNCHRON CX Systems Chemistry Abstracts

Chemistry	C-RP	CR-T	DBIL
Methodology	Latex Turbidimetry	Rate-Jaffe	Diazo
Reaction Type[a] **Analytical Wavelength**	RATE-1 600 nm	RATE-2 520 nm	EP-2 560 nm
Sample Type	Serum/Plasma	Serum/Plasma/Urine	Serum/Plasma
Sample Volume Serum/Plasma Urine CSF ORDAC	 6 µL NA[b] NA 3 µL (Manual ORDAC)	 20 µL 3 µL NA NA	 10 µL NA NA NA
Reagent Volume	300 µL	250 µL	320 µL
Cartridge Volume A B C	 250 µL 50 µL NA	 200 µL NA 50 µL	 310 µL 10 µL NA
Storage	+2°C to +8°C	Room temperature	Room temperature
On-Instrument Stability	60 days	20 days	30 days
Tests per Cartridge	200	300	200 or 300
Reaction Time Window Start from Sample Addition Stop from Sample Addition	 1 sec. 32 sec.	 192 sec. 240 sec.	 414 sec. 446 sec.
Default Unit	mg/dL	mg/dL	mg/dL
Calibration Frequency	30 days	7 days	14 days
Within-lot Cal. Frequency	60 days	30 days	90 days
Analytical Range Serum Urine CSF	 0.2 mg/dL to 25.0 mg/dL NA NA	 0.3 mg/dL to 25 mg/dL 10 mg/dL to 400 mg/dL NA	 0.1 mg/dL to 10 mg/dL NA NA
ORDAC Range	20 mg/dL to 50 mg/dL	NA	NA
Precision Specification (Use the greater number) Serum Urine CSF ORDAC	 0.05 mg/dL or 5.0% NA NA NA	 0.2 mg/dL or 3.0% 2.0 mg/dL or 3.0% NA NA	 0.15 mg/dL or 5.0% NA NA NA
Comment	NA	NA	Reaction starts with Reagent B triggering.

a 1 = Reagent blank not subtracted during calculation of result. 2 = Reagent blank subtracted during calculation of result.

b NA = Not applicable.

Table 22.0 SYNCHRON CX Systems Chemistry Abstracts

Chemistry	DIGN	ETOH	FE
Methodology	Immuno-Turbidimetry	Enzymatic	FerroZine[a]
Reaction Type[b] **Analytical Wavelength**	RATE-1 560 nm	RATE-1 340 nm	EP-2 560 nm
Sample Type	Serum/Plasma	Serum/Plasma/Urine/Whole Blood	Serum/Plasma
Sample Volume Serum/Plasma Whole Blood Urine CSF ORDAC	 15 µL NA[c] NA NA NA	 10 µL 10 µL[d] 10 µL NA NA	 25 µL NA NA NA NA
Reagent Volume	225 µL	275 µL	210 µL
Cartridge Volume A B C	 185 µL 15 µL 25 µL	 200 µL 75 µL NA	 200 µL NA 10 µL
Storage	+2°C to +8°C	+2°C to +8°C	+2°C to +8°C
On-Instrument Stability	30 days	60 days	60 days
Tests per Cartridge	100	150	200
Reaction Time Window Start from Sample Addition Stop from Sample Addition	 416 sec. 464 sec.	 96 sec. 144 sec.	 544 sec. 592 sec.
Default Unit	ng/mL	mg/dL	µg/dL
Calibration Frequency	14 days	30 days	14 days
Within-lot Cal. Frequency	42 days	60 days	NA
Analytical Range Serum Urine CSF Treated Whole Blood	 0.2 ng/mL to 4.5 ng/mL NA NA NA	 5 mg/dL to 600 mg/dL 5 mg/dL to 600 mg/dL NA 10 mg/dL to 700 mg/dL	 5.0 µg/dL to 500 µg/dL NA NA NA
ORDAC Range	NA	NA	NA
Precision Specification (Use the greater number) Serum Urine CSF ORDAC	 0.1 ng/mL or 5.0% NA NA NA	 2.4 mg/dL or 3.0% 2.4 mg/dL or 3.0% NA NA	 2.5 µg/dL or 2.5% NA NA NA
Comment	Run at 37°C only.	Run at 37°C only.	NA

a FerroZine is the trademark of Hach Chemical Co.

b 1 = Reagent blank not subtracted during calculation of result. 2 = Reagent blank subtracted during calculation of result.

c NA = Not applicable.

d Sample size for treated whole blood.

Table 23.0 SYNCHRON CX Systems Chemistry Abstracts

Chemistry	GEN	GGT	GLU
Methodology	Immuno-Turbidimetry	Szasz	UV-Hexokinase
Reaction Type[a] **Analytical Wavelength**	EP-2 380 nm	RATE-1 410 nm	EP-2 340 nm
Sample Type	Serum/Plasma	Serum/Plasma	Serum/Plasma/Urine/CSF
Sample Volume Serum/Plasma Urine CSF ORDAC	 3 µL NA[b] NA NA	 13 µL NA NA 3 µL	 3 µL 3 µL 3 µL NA
Reagent Volume	315 µL	260 µL	300 µL
Cartridge Volume A B C	 245 µL 40 µL 30 µL	 237 µL 23 µL NA	 273 µL 27 µL NA
Storage	+2°C to +8°C	+2°C to +8°C	+2°C to +8°C
On-Instrument Stability	42 days	21 days	30 days
Tests per Cartridge	100	200 or 400	300
Reaction Time Window Start from Sample Addition Stop from Sample Addition	 600 sec. 650 sec.	 60 sec. 180 sec.	 180 sec. 210 sec.
Default Unit	µg/mL	IU/L	mg/dL
Calibration Frequency	14 days	NA	14 days
Within-lot Cal. Frequency	60 days	NA	90 days
Analytical Range Serum Urine CSF	 0.5 µg/mL to 12.0 µg/mL NA NA	 5 IU/L to 750 IU/L NA NA	 5 mg/dL to 700 mg/dL 5 mg/dL to 700 mg/dL 5 mg/dL to 700 mg/dL
ORDAC Range	NA	550 IU/L to 3000 IU/L	NA
Precision Specification (Use the greater number) Serum Urine CSF ORDAC	 0.2 µg/mL or 5.0% NA NA NA	 3.0 IU/L or 3.5% NA NA 10%	 2.0 mg/dL or 2.0% 2.0 mg/dL or 2.0% 2.0 mg/dL or 2.0% NA
Comment	Run at 37°C only.	NA	NA

a 1 = Reagent blank not subtracted during calculation of result. 2 = Reagent blank subtracted during calculation of result.

b NA = Not applicable.

Table 24.0 SYNCHRON CX Systems Chemistry Abstracts

Chemistry	GOT	GPT
Methodology	DGKC	DGKC
Reaction Type[a] **Analytical Wavelength**	RATE-1 340 nm	RATE-1 340 nm
Sample Type	Serum/Plasma	Serum/Plasma
Sample Volume Serum/Plasma Urine CSF ORDAC	 23 µL NA[b] NA 3 µL	 23 µL NA NA 3 µL
Reagent Volume	230 µL	230 µL
Cartridge Volume A B C	 210 µL 20 µL NA	 210 µL 20 µL NA
Storage	+2°C to +8°C	+2°C to +8°C
On-Instrument Stability	5 days	5 days
Tests per Cartridge	250	250
Reaction Time Window Start from Sample Addition Stop from Sample Addition	 90 sec. 210 sec.	 120 sec. 270 sec.
Default Unit	U/L	U/L
Calibration Frequency	NA	NA
Within-lot Cal. Frequency	NA	NA
Analytical Range Serum Urine CSF	 6 U/L to 350 U/L NA NA	 6 U/L to 350 U/L NA NA
ORDAC Range	260 U/L to 2450 U/L	260 U/L to 2450 U/L
Precision Specification (Use the greater number) Serum Urine CSF ORDAC	 3 U/L or 3.5% NA NA 10%	 3 U/L or 3.5% NA NA 10%
Comment	NA	NA

a 1 = Reagent blank not subtracted during calculation of result. 2 = Reagent blank subtracted during calculation of result.

b NA = Not applicable.

Table 25.0 SYNCHRON CX Systems Chemistry Abstracts

Chemistry	HbA1c	
	Hb	A1c
Methodology	Colorimetric	Immuno-Turbidimetry
Reaction Type[a] **Analytical Wavelength**	EP-2 410 nm	EP-2 340 nm
Sample Type	Whole Blood	
Sample Volume Serum/Plasma Urine CSF ORDAC	 25 µL[b] NA[c] NA NA	 8 µL[b] NA NA NA
Reagent Volume	215 µL	253 µL
Cartridge Volume A B C	 215 µL NA NA	 220 µL 33 µL NA
Storage	+2°C to +8°C	+2°C to +8°C
On-Instrument Stability	60 days	30 days
Tests per Cartridge	400	200
Reaction Time Window Start from Sample Addition Stop from Sample Addition	 64 sec. 120 sec.	 600 sec. 664 sec.
Default Unit	g/dL	g/dL
Calibration Frequency	30 days	14 days
Within-lot Cal. Frequency	30 days	30 days
Analytical Range Serum Urine CSF	 6 g/dL to 24 g/dL[b] NA NA	 0.3 g/dL[b] to CAL 5[d] NA NA
ORDAC Range	NA	NA
Precision Specification (Use the greater number) Serum Urine CSF ORDAC	 0.4 %HbA1c[b] or 5.0% NA NA NA	
Comment	Requires sample preparation.	

a 1 = Reagent blank not subtracted during calculation of result. 2 = Reagent blank subtracted during calculation of result.

b Whole blood values.

c NA = Not applicable.

d CAL 5 Value is printed on the HbA1c calibrator value assignment sheet included in the kit.

Table 26.0 SYNCHRON CX Systems Chemistry Abstracts

Chemistry	HDLC
Methodology	Dextran Sulfate
Reaction Type[a] **Analytical Wavelength**	EP-2 520 nm
Sample Type	Serum/Plasma
Sample Volume Serum/Plasma Urine CSF ORDAC	 5 µL NA[b] NA NA
Reagent Volume	300 µL
Cartridge Volume A B C	 290 µL NA 10 µL
Storage	+2°C to +8°C
On-Instrument Stability	30 days
Tests per Cartridge	300
Reaction Time Window Start from Sample Addition Stop from Sample Addition	 320 sec. 352 sec.
Default Unit	mg/dL
Calibration Frequency	14 days
Within-lot Cal. Frequency	90 days
Analytical Range Serum Urine CSF	 5 mg/dL to 90 mg/dL NA NA
ORDAC Range	NA
Precision Specification (Use the greater number) Serum Urine CSF ORDAC	 3.0 mg/dL or 3.0% NA NA NA
Comment	Run at 37°C only. Requires Sample preparation.

a 1 = Reagent blank not subtracted during calculation of result. 2 = Reagent blank subtracted during calculation of result.

b NA = Not applicable.

Table 27.0 SYNCHRON CX Systems Chemistry Abstracts

Chemistry	HDLD	IBCT	IgA
Methodology	Homogeneous	FerroZine[a]	Immuno-Turbidimetry
Reaction Type[b] **Analytical Wavelength**	EP-2 560 nm	EP-2 560 nm	EP-2 340 nm
Sample Type	Serum/Plasma	Serum/Plasma	Serum
Sample Volume Serum/Plasma Urine CSF ORDAC	 3 µL NA[c] NA NA	 25 µL NA NA NA	 8 µL NA NA NA
Reagent Volume	280 µL	210 µL	200 µL
Cartridge Volume A B C	 210 µL 70 µL NA	 200 µL NA 10 µL	 NA 200 µL NA
Storage	+2°C to +8°C	+2°C to +8°C	+2°C to +8°C
On-Instrument Stability	60 days	60 days	30 days
Tests per Cartridge	200	100	70
Reaction Time Window Start from Sample Addition Stop from Sample Addition	 704 sec. 720 sec.	 544 sec. 592 sec.	 500 sec. 560 sec.
Default Unit	mg/dL	µg/dL	mg/dL
Calibration Frequency	30 days	14 days	14 days
Within-lot Cal. Frequency	90 days	NA	NA
Analytical Range Serum Urine CSF	 5 mg/dL to 135 mg/dL NA NA	 10.0 µg/dL to 1000 µg/dL NA NA	 CAL 1 Value to CAL 5 Value NA NA
ORDAC Range	NA	NA	NA
Precision Specification (Use the greater number) Serum Urine CSF ORDAC	 3.0 mg/dL or 3.0% NA NA NA	 10.0 µg/dL or 4.0% NA NA NA	 10.0 mg/dL or 5.0% NA NA NA
Comment	Run at 37°C only.	Requires sample preparation.	Sample dilution required.

a FerroZine is the trademark of Hach Chemical Co.

b 1 = Reagent blank not subtracted during calculation of result. 2 = Reagent blank subtracted during calculation of result.

c NA = Not applicable.

Table 28.0 SYNCHRON CX Systems Chemistry Abstracts

Chemistry	IgG	IgM	LAC
Methodology	Immuno-Turbidimetry	Immuno-Turbidimetry	Enzymatic
Reaction Type[a] **Analytical Wavelength**	EP-2 340 nm	EP-2 340 nm	EP-2 520 nm
Sample Type	Serum	Serum	Plasma/CSF
Sample Volume Serum/Plasma Urine CSF ORDAC	 4 µL NA[b] NA NA	 20 µL NA NA NA	 3 µL NA 3 µL NA
Reagent Volume	200 µL	200 µL	327 µL
Cartridge Volume A B C	 NA 200 µL NA	 NA 200 µL NA	 NA 327 µL NA
Storage	+2°C to +8°C	+2°C to +8°C	+2°C to +8°C
On-Instrument Stability	30 days	30 days	14 days
Tests per Cartridge	70	70	35
Reaction Time Window Start from Sample Addition Stop from Sample Addition	 500 sec. 560 sec.	 500 sec. 560 sec.	 220 sec. 270 sec.
Default Unit	mg/dL	mg/dL	mmol/L
Calibration Frequency	14 days	14 days	7 days
Within-lot Cal. Frequency	NA	NA	NA
Analytical Range Serum Urine CSF	 CAL 1 Value to CAL 5 Value NA NA	 CAL 1 Value to CAL 5 Value NA NA	 0.3 mmol/L to 11.1 mmol/L[c] NA 0.3 to 11.1 mmol/L
ORDAC Range	NA	NA	NA
Precision Specification (Use the greater number) Serum Urine CSF ORDAC	 5.0 mg/dL or 5.0% NA NA NA	 10.0 mg/dL or 5.0% NA NA NA	 0.13 mmol/L[c] or 3.0% NA 0.13 mmol/L or 3% NA
Comment	Sample dilution required.	Sample dilution required.	Sodium Fluoride and Potassium Oxalate plasma only.

a 1 = Reagent blank not subtracted during calculation of result. 2 = Reagent blank subtracted during calculation of result.

b NA = Not applicable.

c Plasma values.

Table 29.0 SYNCHRON CX Systems Chemistry Abstracts

Chemistry	LD-L	LDLD
Methodology	Lactate to Pyruvate	Colorimetric
Reaction Type[a] **Analytical Wavelength**	RATE-1 340 nm	EP-2 560 nm
Sample Type	Serum/Plasma	Serum/Plasma
Sample Volume Serum/Plasma Urine CSF ORDAC	 13 µL NA NA 3 µL	 3 µL NA NA NA
Reagent Volume	260 µL	280 µL
Cartridge Volume A B C	 251 µL NA 9 µL	 210 µL 70 µL NA
Storage	+2°C to +8°C	+2°C to +8°C
On-Instrument Stability	30 days	30 days
Tests per Cartridge	200 or 300	100
Reaction Time Window Start from Sample Addition Stop from Sample Addition	 60 sec. 125 sec.	 656 sec. 720 sec.
Default Unit	IU/L	mg/dL
Calibration Frequency	NA	30 days
Within-lot Cal. Frequency	NA	60 days
Analytical Range Serum Urine CSF	 5 IU/L to 750 IU/L NA NA	 10 mg/dL to 550 mg/dL NA NA
ORDAC Range	600 IU/L to 2700 IU/L	NA
Precision Specification (Use the greater number) Serum Urine CSF ORDAC	 5.0 IU/L or 3.5% NA NA 10%	 3 mg/dL or 3.0% NA NA NA
Comment	NA	NA

a 1 = Reagent blank not subtracted during calculation of result. 2 = Reagent blank subtracted during calculation of result.

Table 30.0 SYNCHRON CX Systems Chemistry Abstracts

Chemistry	LD-P	LIPA
Methodology	Pyruvate to Lactate	Enzymatic
Reaction Type[a] **Analytical Wavelength**	RATE-1 340 nm	RATE-1 560 nm
Sample Type	Serum/Plasma	Serum/Plasma
Sample Volume Serum/Plasma Urine CSF ORDAC	 5 µL NA[b] NA 3 µL	 4 µL NA NA NA
Reagent Volume	250 µL	270 µL
Cartridge Volume A B C	 242 µL 8 µL NA	 NA 200 µL 70 µL
Storage	+2°C to +8°C	+2°C to +8°C
On-Instrument Stability	30 days	14 days
Tests per Cartridge	200	30
Reaction Time Window Start from Sample Addition Stop from Sample Addition	 20 sec. 60 sec.	 380 sec. 490 sec.
Default Unit	IU/L	U/L
Calibration Frequency	NA	5 days
Within-lot Cal. Frequency	NA	NA
Analytical Range Serum Urine CSF	 20 IU/L to 2500 IU/L NA NA	 5 U/L to 600 U/L NA NA
ORDAC Range	1800 IU/L to 3800 IU/L	NA
Precision Specification (Use the greater number) Serum Urine CSF ORDAC	 15.0 IU/L or 3.5% NA NA 10%	 5 U/L or 5% NA NA NA
Comment	NA	Run at 37°C only.

a 1 = Reagent blank not subtracted during calculation of result. 2 = Reagent blank subtracted during calculation of result.

b NA = Not applicable.

Table 31.0 SYNCHRON CX Systems Chemistry Abstracts

Chemistry	M-TP	MA	METD
Methodology	Pyrogallol Red	Immuno-Turbidimetry	EIA
Reaction Type[a] **Analytical Wavelength**	EP-2 600 nm	EP-2 380 nm	RATE-1 340 nm
Sample Type	CSF/Urine	Urine	Urine
Sample Volume Serum/Plasma Urine CSF ORDAC	 NA[b] 10 µL 5 µL NA	 NA 10 µL NA 3 µL	 NA 10 µL NA NA
Reagent Volume	300 µL	240 µL	250 µL
Cartridge Volume A B C	 NA 300 µL NA	 215 µL 25 µL NA	 200 µL 50 µL NA
Storage	+2°C to +8°C	+2°C to +8°C	+2°C to +8°C
On-Instrument Stability	30 days	60 days	90 days
Tests per Cartridge	50	100	250
Reaction Time Window Start from Sample Addition Stop from Sample Addition	 240 sec. 270 sec.	 312 sec. 376 sec.	 96 sec. 144 sec.
Default Unit	mg/dL	mg/dL	mAbs/min
Calibration Frequency	14 days	30 days	14 days
Within-lot Cal. Frequency	90 days	60 days	90 days
Analytical Range Serum Urine CSF	 NA 6 mg/dL to 150 mg/dL 6 mg/dL to 300 mg/dL	 NA 0.2 mg/dL to 30 mg/dL NA	 NA NA NA
ORDAC Range	NA	24 mg/dL to 97 mg/dL	NA
Precision Specification (Use the greater number) Serum Urine CSF ORDAC	 NA 2 mg/dL or 4% 2 mg/dL or 4% NA	 NA 0.125 mg/dL or 5.4% NA 5.4%	 NA 2.0% NA NA
Comment	Run at 37°C only.	Run at 37°C only.	Qualitative, POS/NEG Run at 37°C only.

a 1 = Reagent blank not subtracted during calculation of result. 2 = Reagent blank subtracted during calculation of result.

b NA = Not applicable.

Table 32.0 SYNCHRON CX Systems Chemistry Abstracts

Chemistry	METQ	MG	OP
Methodology	EIA	Calmagite	EIA
Reaction Type[a] **Analytical Wavelength**	RATE-1 340 nm	EP-2 520 nm	RATE-1 340 nm
Sample Type	Urine	Serum/Plasma/Urine	Urine
Sample Volume Serum/Plasma Urine CSF ORDAC	 NA[b] 10 µL NA NA	 3 µL 3 µL NA NA	 NA 20 µL NA NA
Reagent Volume	250 µL	308 µL	250 µL
Cartridge Volume A B C	 200 µL 50 µL NA	 280 µL 28 µL NA	 200 µL 50 µL NA
Storage	+2°C to +8°C	Room temperature	+2°C to +8°C
On-Instrument Stability	90 days	7 days	90 days
Tests per Cartridge	250	100	250
Reaction Time Window Start from Sample Addition Stop from Sample Addition	 96 sec. 144 sec.	 64 sec. 96 sec.	 96 sec. 144 sec.
Default Unit	mAbs/min	mg/dL	mAbs/min
Calibration Frequency	14 days	7 days	14 days
Within-lot Cal. Frequency	90 days	90 days	90 days
Analytical Range Serum Urine CSF	 NA NA NA	 0.1 mg/dL to 7.0 mg/dL 0.1 mg/dL to 7.0 mg/dL NA	 NA NA NA
ORDAC Range	NA	NA	NA
Precision Specification (Use the greater number) Serum Urine CSF ORDAC	 NA 2.0% NA NA	 0.08 mg/dL or 2.0% 0.08 mg/dL or 2.0% NA NA	 NA 2.0% NA NA
Comment	Qualitative, POS/NEG Run at 37°C only.	Urine Samples require a 1:10 dilution.	Qualitative, POS/NEG Run at 37°C only.

a 1 = Reagent blank not subtracted during calculation of result. 2 = Reagent blank subtracted during calculation of result.

b NA = Not applicable.

Table 33.0 SYNCHRON CX Systems Chemistry Abstracts

Chemistry	OP2	PAB	PAM
Methodology	EIA	Immuno-Turbidimetry	Immuno-Inhibition EPS-Substrate
Reaction Type[a] **Analytical Wavelength**	RATE-1 340 nm	EP-2 340 nm	RATE-1 410 nm
Sample Type	Urine	Serum/Plasma	Serum/Plasma/Urine
Sample Volume Serum/Plasma Urine CSF ORDAC	 NA[b] 5 µL NA NA	 3 µL NA NA NA	 10 µL 10 µL NA 3 µL
Reagent Volume	250 µL	210 µL	240 µL
Cartridge Volume A B C	 200 µL 50 µL NA	 200 µL NA 10 µL	 NA 200 µL 40 µL
Storage	+2°C to +8°C	+2°C to +8°C	+2°C to +8°C
On-Instrument Stability	90 days	60 days	30 days
Tests per Cartridge	250	100	60
Reaction Time Window Start from Sample Addition Stop from Sample Addition	 96 sec. 144 sec.	 352 sec. 384 sec.	 304 sec. 368 sec.
Default Unit	mAbs/min	mg/dL	U/L
Calibration Frequency	14 days	30 days	NA
Within-lot Cal. Frequency	90 days	60 days	NA
Analytical Range Serum Urine CSF	 NA NA NA	 2 mg/dL to 60 mg/dL NA NA	 5 U/L to 600 U/L 5 U/L to 600 U/L NA
ORDAC Range	NA	NA	480 U/L to 1800 U/L
Precision Specification (Use the greater number) Serum Urine CSF ORDAC	 NA 2.0% NA NA	 0.92 mg/dL or 5.25% NA NA NA	 5 U/L or 3.5% 5 U/L or 3.5% NA 10%
Comment	Qualitative, POS/NEG Run at 37°C only.	Run at 37°C only.	Run at 37°C only.

a 1 = Reagent blank not subtracted during calculation of result. 2 = Reagent blank subtracted during calculation of result.

b NA = Not applicable.

Table 34.0 SYNCHRON CX Systems Chemistry Abstracts

Chemistry	PCP	PHE	PHOS/PO4
Methodology	EIA	Immuno-Turbidimetry	Phospho-Molybdate
Reaction Type[a] **Analytical Wavelength**	RATE-1 340 nm	RATE-1 340 nm	EP-2 340 nm
Sample Type	Urine	Serum/Plasma	Serum/Plasma/Urine
Sample Volume Serum/Plasma Urine CSF ORDAC	 NA[b] 20 µL NA NA	 3 µL NA NA NA	 4 µL 4 µL NA NA
Reagent Volume	250 µL	295 µL	267 µL
Cartridge Volume A B C	 200 µL 50 µL NA	 210 µL 55 µL 30 µL	 243 µL 24 µL NA
Storage	+2°C to +8°C	+2°C to +8°C	Room temperature
On-Instrument Stability	90 days	42 days	30 days
Tests per Cartridge	250	100	300
Reaction Time Window Start from Sample Addition Stop from Sample Addition	 96 sec. 144 sec.	 112 sec. 160 sec.	 120 sec. 150 sec.
Default Unit	mAbs/min	µg/mL	mg/dL
Calibration Frequency	14 days	14 days	14 days
Within-lot Cal. Frequency	90 days	60 days	60 days
Analytical Range Serum Urine CSF	 NA NA NA	 5.0 µg/mL to 80.0 µg/mL NA NA	 1 mg/dL to 12 mg/dL 1 mg/dL to 12 mg/dL NA
ORDAC Range	NA	NA	NA
Precision Specification (Use the greater number) Serum Urine CSF ORDAC	 NA 2.0% NA NA	 1.0 µg/mL or 4.0% NA NA NA	 0.2 mg/dL or 2.0% 0.2 mg/dL or 2.0% NA NA
Comment	Qualitative, POS/NEG Run at 37°C only.	Run at 37°C only.	Urine Samples require a 1:10 dilution.

a 1 = Reagent blank not subtracted during calculation of result. 2 = Reagent blank subtracted during calculation of result.

b NA = Not applicable.

Table 35.0 SYNCHRON CX Systems Chemistry Abstracts

Chemistry	PHS	PHY	PROX
Methodology	Phospho-Molybdate	Immuno-Turbidimetry	EIA
Reaction Type[a] **Analytical Wavelength**	EP-2 340 nm	RATE-1 340 nm	RATE-1 340 nm
Sample Type	Serum/Plasma/Urine	Serum/Plasma	Urine
Sample Volume Serum/Plasma Urine CSF ORDAC	 4 µL 4 µL NA[b] NA	 3 µL NA NA NA	 NA 10 µL NA NA
Reagent Volume	267 µL	302 µL	295 µL
Cartridge Volume A B C	 243 µL 24 µL NA	 230 µL 40 µL 32 µL	 200 µL 50 µL NA
Storage	Room temperature	+2°C to +8°C	+2°C to +8°C
On-Instrument Stability	30 days	42 days	90 days
Tests per Cartridge	300	100	250
Reaction Time Window Start from Sample Addition Stop from Sample Addition	 256 sec. 296 sec.	 112 sec. 144 sec.	 96 sec. 144 sec.
Default Unit	mg/dL	µg/mL	mAbs/min
Calibration Frequency	14 days	14 days	14 days
Within-lot Cal. Frequency	60 days	60 days	90 days
Analytical Range Serum Urine CSF	 1 mg/dL to 12 mg/dL 10 mg/dL to 120 mg/dL NA	 2.5 µg/mL to 40.0 µg/mL NA NA	 NA NA NA
ORDAC Range	NA	NA	NA
Precision Specification (Use the greater number) Serum Urine CSF ORDAC	 0.2 mg/dL or 2.0% 2.0 mg/dL or 2.0% NA NA	 0.5 µg/mL or 4.0% NA NA NA	 NA 2.0% NA NA
Comment	Urine Samples require a 1:10 dilution for CX CE/Delta Systems.	Run at 37°C only.	Qualitative, POS/NEG Run at 37°C only.

a 1 = Reagent blank not subtracted during calculation of result. 2 = Reagent blank subtracted during calculation of result.

b NA = Not applicable.

Table 36.0 SYNCHRON CX Systems Chemistry Abstracts

Chemistry	RF	SALY	T4
Methodology	Immuno-Turbidimetry	Enzymatic (Salicylate Hydroxylase)	CEDIA[a]
Reaction Type[b] **Analytical Wavelength**	RATE-1 380 nm	EP-2 340 nm	RATE-1 410 nm
Sample Type	Serum/Plasma	Serum/Plasma	Serum
Sample Volume Serum/Plasma Urine CSF ORDAC	 12 µL NA[c] NA 6 µL (Manual ORDAC)	 4 µL NA NA NA	 9 µL NA NA NA
Reagent Volume	300 µL	225 µL	260 µL
Cartridge Volume A B C	 250 µL NA 50 µL	 NA 150 µL 75 µL	 200 µL 60 µL NA
Storage	+2°C to +8°C	+2°C to +8°C	+2°C to +8°C
On-Instrument Stability	60 days	60 days	30 days
Tests per Cartridge	100	45	200
Reaction Time Window Start from Sample Addition Stop from Sample Addition	 0 sec. 48 sec.	 320 sec. 368 sec.	 576 sec. 640 sec.
Default Unit	IU/mL	mg/dL	µg/dL
Calibration Frequency	30 days	30 days	24 hours
Within-lot Cal. Frequency	60 days	90 days	NA
Analytical Range Serum Urine CSF	 20 IU/mL to 800 IU/mL NA NA	 4.0 mg/dL to 100 mg/dL NA NA	 2.0 µg/dL to Hi CAL Value NA NA
ORDAC Range	720 IU/mL to 2.0 × CAL 6 Value	NA	NA
Precision Specification (Use the greater number) Serum Urine CSF ORDAC	 10.0 IU/mL or 4.0% NA NA NA	 1.5 mg/dL or 5.0% NA NA NA	 0.4 µg/dL or 5.0% NA NA NA
Comment	Run at 37°C only.	Run at 37°C only. Calibrator is included in the Reagent kit.	Reconstitute reagents immediately upon removal from refrigerator.

a CEDIA is a registered trademark of Boehringer Mannheim Corporation.

b 1 = Reagent blank not subtracted during calculation of result. 2 = Reagent blank subtracted during calculation of result.

c NA = Not applicable.

Table 37.0 SYNCHRON CX Systems Chemistry Abstracts

Chemistry	TBIL	TG	TG-B
Methodology	Jendrassik-Grof	Enzymatic (GPO-Trinder)	Enzymatic (GPO-Trinder) Glycerol Blanked
Reaction Type[a] **Analytical Wavelength**	EP-2 520 nm	EP-2 520 nm	EP-2 520 nm
Sample Type	Serum/Plasma	Serum/Plasma	Serum/Plasma
Sample Volume Serum/Plasma Urine CSF ORDAC	 8 µL NA[b] NA NA	 3 µL NA NA NA	 3 µL NA NA NA
Reagent Volume	280 µL	300 µL	300 µL
Cartridge Volume A B C	 255 µL 25 µL NA	 285 µL 15 µL NA	 275 µL 15 µL 10 µL
Storage	Room temperature	+2°C to +8°C	+2°C to +8°C
On-Instrument Stability	30 days	30 days	30 days
Tests per Cartridge	300 or 400	300	300
Reaction Time Window Start from Sample Addition Stop from Sample Addition	 120 sec. 150 sec.	 352 sec. 384 sec.	 544 sec. 576 sec.
Default Unit	mg/dL	mg/dL	mg/dL
Calibration Frequency	14 days	14 days	14 days
Within-lot Cal. Frequency	90 days	90 days	90 days
Analytical Range Serum Urine CSF	 0.1 mg/dL to 30 mg/dL NA NA	 10 mg/dL to 1000 mg/dL NA NA	 10 mg/dL to 1000 mg/dL NA NA
ORDAC Range	NA	NA	NA
Precision Specification (Use the greater number) Serum Urine CSF ORDAC	 0.15 mg/dL or 3.0% NA NA NA	 5.0 mg/dL or 3.0% NA NA NA	 5.0 mg/dL or 3.0% NA NA NA
Comment	Mix 0.1 mL of C into B (for 300 tests). Mix 0.2 mL of C into B (for 400 tests).	Run at 37°C only. Mix C to A.	Run at 37°C only.

a 1 = Reagent blank not subtracted during calculation of result. 2 = Reagent blank subtracted during calculation of result.

b NA = Not applicable.

Table 38.0 SYNCHRON CX Systems Chemistry Abstracts

Chemistry	THC	THC2	THC5
Methodology	EIA	EIA	EIA
Reaction Type[a] **Analytical Wavelength**	RATE-1 340 nm	RATE-1 340 nm	RATE-1 340 nm
Sample Type	Urine	Urine	Urine
Sample Volume Serum/Plasma Urine CSF ORDAC	 NA[b] 20 µL NA NA	 NA 20 µL NA NA	 NA 25 µL NA NA
Reagent Volume	250 µL	250 µL	250 µL
Cartridge Volume A B C	 200 µL 50 µL NA	 200 µL 50 µL NA	 200 µL 50 µL NA
Storage	+2°C to +8°C	+2°C to +8°C	+2°C to +8°C
On-Instrument Stability	60 days	60 days	90 days
Tests per Cartridge	150	150	250
Reaction Time Window Start from Sample Addition Stop from Sample Addition	 96 sec. 144 sec.	 96 sec. 144 sec.	 96 sec. 144 sec.
Default Unit	mAbs/min	mAbs/min	mAbs/min
Calibration Frequency	14 days	14 days	14 days
Within-lot Cal. Frequency	90 days	90 days	90 days
Analytical Range Serum Urine CSF	 NA NA NA	 NA NA NA	 NA NA NA
ORDAC Range	NA	NA	NA
Precision Specification (Use the greater number) Serum Urine CSF ORDAC	 NA 2.0% NA NA	 NA 2.0% NA NA	 NA 2.0% NA NA
Comment	Qualitative, POS/NEG Run at 37°C only.	Qualitative, POS/NEG Run at 37°C only.	Qualitative, POS/NEG Run at 37°C only.

a 1 = Reagent blank not subtracted during calculation of result. 2 = Reagent blank subtracted during calculation of result.

b NA = Not applicable.

Table 39.0 SYNCHRON CX Systems Chemistry Abstracts

Chemistry	THE	TOB	TP
Methodology	Immuno-Turbidimetry	Immuno-Turbidimetry	Biuret
Reaction Type[a] **Analytical Wavelength**	EP-2 340 nm	EP-2 340 nm	EP-2 560 nm
Sample Type	Serum/Plasma	Serum/Plasma	Serum/Plasma
Sample Volume Serum/Plasma Urine CSF ORDAC	 3 µL NA[b] NA NA	 3 µL NA NA NA	 6 µL NA NA NA
Reagent Volume	292 µL	270 µL	300 µL
Cartridge Volume A B C	 230 µL 30 µL 32 µL	 200 µL 40 µL 30 µL	 300 µL NA NA
Storage	+2°C to +8°C	+2°C to +8°C	Room temperature
On-Instrument Stability	42 days	42 days	20 days
Tests per Cartridge	100	100	300
Reaction Time Window Start from Sample Addition Stop from Sample Addition	 512 sec. 562 sec.	 380 sec. 430 sec.	 150 sec. 180 sec.
Default Unit	µg/mL	µg/mL	g/dL
Calibration Frequency	14 days	14 days	7 days
Within-lot Cal. Frequency	60 days	60 days	90 days
Analytical Range Serum Urine CSF	 2.0 µg/mL to 40.0 µg/mL NA NA	 0.5 µg/mL to 12.0 µg/mL NA NA	 3 g/dL to 12 g/dL NA NA
ORDAC Range	NA	NA	NA
Precision Specification (Use the greater number) Serum Urine CSF ORDAC	 0.5 µg/mL or 4.0% NA NA NA	 0.2 µg/mL or 4.0% NA NA NA	 0.3 g/dL or 3.0% NA NA NA
Comment	Run at 37°C only.	Run at 37°C only.	Run at 37°C only.

a 1 = Reagent blank not subtracted during calculation of result. 2 = Reagent blank subtracted during calculation of result.

b NA = Not applicable.

Table 40.0 SYNCHRON CX Systems Chemistry Abstracts

Chemistry	TRF	TU	UREA
Methodology	Immuno-Turbidimetry	CEDIA[a]	UV-Rate
Reaction Type[b] **Analytical Wavelength**	EP-2 340 nm	RATE-1 410 nm	RATE-1 340 nm
Sample Type	Serum	Serum	Serum/Plasma/Urine
Sample Volume Serum/Plasma Urine CSF ORDAC	 10 µL NA[c] NA NA	 15 µL NA NA NA	 3 µL 3 µL NA NA
Reagent Volume	200 µL	252 µL	300 µL
Cartridge Volume A B C	 NA 200 µL NA	 209 µL 43 µL NA	 285 µL 15 µL NA
Storage	+2°C to +8°C	+2°C to +8°C	+2°C to +8°C
On-Instrument Stability	30 days	21 days	30 days
Tests per Cartridge	70	250	300
Reaction Time Window Start from Sample Addition Stop from Sample Addition	 500 sec. 560 sec.	 450 sec. 510 sec.	 30 sec. 60 sec.
Default Unit	mg/dL	%	mmol/L
Calibration Frequency	14 days	24 hours	24 hours
Within-lot Cal. Frequency	NA	NA	30 days
Analytical Range Serum Urine CSF	 CAL 1 Value to CAL 5 Value NA NA	 Lo CAL Value to Hi CAL Value NA NA	 1.8 mmol/L to 35.7 mmol/L 1.8 mmol/L to 35.7 mmol/L NA
ORDAC Range	NA	NA	NA
Precision Specification (Use the greater number) Serum Urine CSF ORDAC	 5.0 mg/dL or 5.0% NA NA NA	 0.65% or 2.5% NA NA NA	 0.7 mmol/L or 3.0% 0.7 mmol/L or 3.0% NA NA
Comment	Sample Dilution required.	Reconstitute reagents immediately upon removal from refrigerator.	Urine Samples require a 1:10 dilution.

a CEDIA is a registered trademark of Boehringer Mannheim Corporation.

b 1 = Reagent blank not subtracted during calculation of result. 2 = Reagent blank subtracted during calculation of result.

c NA = Not applicable.

Table 41.0 SYNCHRON CX Systems Chemistry Abstracts

Chemistry	URIC	VANC	VPA
Methodology	Enzymatic Trinder	Immuno-Turbidimetry	Immuno-Turbidimetry
Reaction Type[a] **Analytical Wavelength**	EP-2 520 nm	RATE-1 340 nm	RATE-1 600 nm
Sample Type	Serum/Plasma/Urine	Serum/Plasma	Serum/Plasma
Sample Volume Serum/Plasma Urine CSF ORDAC	 12 µL 12 µL NA[b] NA	 3 µL NA NA NA	 3 µL NA NA NA
Reagent Volume	300 µL	312 µL	312 µL
Cartridge Volume A B C	 270 µL 30 µL NA	 230 µL 50 µL 32 µL	 287 µL NA 25 µL
Storage	+2°C to +8°C	+2°C to +8°C	+2°C to +8°C
On-Instrument Stability	30 days	42 days	42 days
Tests per Cartridge	300	100	100
Reaction Time Window Start from Sample Addition Stop from Sample Addition	 440 sec. 480 sec.	 32 sec. 64 sec.	 336 sec. 400 sec.
Default Unit	mg/dL	µg/mL	µg/mL
Calibration Frequency	14 days	14 days	14 days
Within-lot Cal. Frequency	90 days	42 days	60 days
Analytical Range Serum Urine CSF	 0.5 mg/dL to 12 mg/dL 0.5 mg/dL to 12 mg/dL NA	 3.5 µg/mL to 50.0 µg/mL NA NA	 10.0 µg/mL to 150.0 µg/mL NA NA
ORDAC Range	NA	NA	NA
Precision Specification (Use the greater number) Serum Urine CSF ORDAC	 0.15 mg/dL or 2.0% 0.15 mg/dL or 2.0% NA NA	 1.3 µg/mL or 4.0% NA NA NA	 3.0 µg/mL or 5.0% NA NA NA
Comment	Urine Samples require a 1:10 dilution.	Mix Cartridge well before placing on instrument.	Mix Cartridge well before placing on instrument. Run at 37°C only.

a 1 = Reagent blank not subtracted during calculation of result. 2 = Reagent blank subtracted during calculation of result.

b NA = Not applicable.

Calibrators, Controls, and Solutions

Table 42.0 Calibrators

Calibrator	Part Number	Use	Open Bottle Storage Temp.	Open Bottle Stability	Prep?
Calibration Standard 1 (CX5 only)	443360	NA, K, CL, CO2	+18°C to +25°C	30 days	No
Calibration Standard 2 (CX5 only)	443365	NA, K, CL, CO2	+18°C to +25°C	30 days	No
Calibrator Level 1 (Delta only)	465908	NA, K, CL, CO2, BUN, BUN3, CA, CA3, CALC, CREA, CRE3, GLU, GLU3	+18°C to +25°C	30 days	No
Calibrator Level 2 (Delta only)	465909	NA, K, CL, CO2, BUN, BUN3, CA, CA3, CALC, CREA, CRE3, GLU, GLU3	+18°C to +25°C	30 days	No
Calibrator Level 3 (Delta only)	465910	NA, K, CL, CO2, BUN, BUN3, CA, CA3, CALC, CREA, CRE3, GLU, GLU3	+18°C to +25°C	30 days	No
CX MULTI™ Calibrator	442600	ALB, BUN, CA, CHOL, CREA, CR-T, GLU, LAC, MG, PHOS, PHS, PO4, TG, TG-B, TP, UREA, URIC	+2°C to +8°C	20 days	No
CX® C-RP Calibrator	969739	C-RP	+2°C to +8°C	Expiration date	No
SYNCHRON Systems Ammonia Calibrator	439770 (Reagent Kit)	AMM	+2°C to +8°C	60 days	No
SYNCHRON Systems Bilirubin Calibrator	465915	DBIL, TBIL	+2°C to +8°C	24 hrs.	No
SYNCHRON Systems CAL 5 Plus	469965	ASO-	+2°C to +8°C	Expiration date	No
SYNCHRON Systems CRP Calibrator Levels 1-5	445915	CRP	+2°C to +8°C	60 days	No
SYNCHRON Systems DAT Negative Urine Calibrator	445803	AMPH, BARB, BENZ, BNZG, COCM, METD, METQ, OP, OP2, PCP, PROX, THC, THC2, THC5	+2°C to +8°C	Expiration date	No
SYNCHRON Systems DAT Multi-Drug Urine Calibrator					
Low	474970	AMPH, BARB, BENZ, BNZG, COCM, METD, METQ, OP2, PCP, PROX	+2°C to +8°C	Expiration date	No
High	474973	AMPH, BARB, BENZ, BNZG, COCM, METD, METQ, OP2, PCP, PROX			
SYNCHRON Systems ETOH Calibrator	474994	ETOH	+2°C to +8°C	Expiration date	No
SYNCHRON Systems OP 300 Calibrator					
Low	474982	OP	+2°C to +8°C	Expiration date	No
High	474985	OP			
SYNCHRON Systems Drug CAL 1	469600	CAR, PHE, PHY, THE, VPA	+2°C to +8°C	Expiration date	No
SYNCHRON Systems Drug CAL 2	469630	ACTM, DIGN	+2°C to +8°C	Expiration date	No
SYNCHRON Systems Drug CAL 3 Plus	471080	GEN, TOB	+2°C to +8°C	Expiration date	No
SYNCHRON Systems FE/IBCT Calibrator	442772	FE, IBCT	+2°C to +26°C	Expiration date	No
SYNCHRON Systems HbA1c Calibrator	650262 (Reagent Kit)	HB, A1C	+15°C to +25°C +2°C to +8°C -15°C to -20°C	8 hours 48 hours 90 days	Yes
SYNCHRON Systems HDL Cholesterol Calibrator	467850	HDLC	+2°C to +8°C	60 days	No
SYNCHRON Systems Hemolyzing Reagent	472137	Level 1 Calibrator for A1C and A1C2	+2°C to +8°C	Expiration date	No

Table 42.0 Calibrators, Continued

Calibrator	Part Number	Use	Open Bottle Storage Temp.	Open Bottle Stability	Prep?
SYNCHRON Systems LDLD Calibrator	969706 (Reagent Kit)	LDLD	+2°C to +8°C -80°C	14 days 30 days	Yes
SYNCHRON Systems Lipid Calibrators Levels 1 and 2	650218	HDLD	+2°C to +8°C	60 days	No
SYNCHRON CX Systems MA Calibrator	475057	MA	+2°C to +8°C	Expiration date	No
SYNCHRON Systems Microprotein Calibrator	445930	M-TP	+2°C to +8°C	60 days	No
SYNCHRON CX Systems PAB Calibrator	475033	PAB	+2°C to +8°C	Expiration date	No
SYNCHRON Systems Protein Calibrator Levels 1 and 2	450202	TP3	+2°C to +8°C	60 days	No
SYNCHRON Systems Salicylate Calibrator	378194 (Reagent Kit)	SALY	+2°C to +8°C	30 days	No
SYNCHRON Systems **THC Urine Calibrator** 20 ng/mL 50 ng/mL 100 ng/mL 200 ng/mL	 464390 445809 445811 445814	 THC2 THC2, THC5 THC5, THC THC	+2°C to +8°C	Expiration date	No
SYNCHRON CX Systems CX RF Calibrator Levels 1 - 6	471225	RF	+2°C to +8°C	60 days	No
SYNCHRON Systems Vancomycin Calibrator Set	378045	VANC	+2°C to +8°C	Expiration date	No
Immuno Protein Calibrator Levels 1 - 5 (Includes CX® PRO Systems)	442840	IGG, IGM, IGA, TRF	+2°C to +8°C	60 days	No
LIPA Calibrator	465101 (Reagent Kit)	LIPA	+2°C to +8°C	45 days	Yes
SYNCHRON® Enzyme Validator Set	441350	AST-, ALT-, CK-	-15°C to -20°C	60 days	No
T4 Calibrator Levels 1 - 2	445995 (Reagent Kit)	T4	+2°C to +8°C	30 days	Yes
TU Calibrator Levels 1 - 2	445999 (Reagent Kit)	TU	+2°C to +8°C	21 days	Yes

Table 43.0 Controls

Control	Part Number	Use	Open Bottle Storage Temp.	Open Bottle Stability	Prep?
SYNCHRON® Systems Ammonia/Alcohol Control					
Level 1	465990	AMM, ETOH	+2°C to +8°C	30 days	No
Level 2	465993	AMM, ETOH			
Level 3	465996	AMM, ETOH			
SYNCHRON Systems DAT Drug Free Urine Control	469945	AMPH, BARB, BENZ, BNZG, COCM, METD, METQ, OP, OP2, PCP, PROX, THC, THC2, THC5	+2°C to +8°C	Expiration date	No
SYNCHRON Systems DAT Multi-Drug Urine Control					
Low	474976	AMPH, BARB, BENZ, BNZG, COCM, METD, METQ, OP2, PCP, PROX	+2°C to +8°C	Expiration date	No
High	474979	AMPH, BARB, BENZ, BNZG, COCM, METD, METQ, OP2, PCP, PROX			
SYNCHRON Systems Urine OP 300 Control					
Low	474988	OP	+2°C to +8°C	Expiration date	No
High	474991	OP			
SYNCHRON Systems THC Urine Control					
10 ng/mL	472107	THC2	+2°C to +8°C	Expiration date	No
20 ng/mL	465914	THC5			
40 ng/mL	472110	THC2			
75 ng/mL	465912	THC5, THC			
125 ng/mL	465939	THC			
Decision® Control Serums					
Level 1	667270	Multianalyte	+2°C to +8°C	20 days	No
Level 2	667280	Multianalyte			
Level 3	667290	Multianalyte			
Multilevel	667420	Multianalyte			
I.D. -Zone® CK Control	667990	CKMB	+2°C to +8°C	20 days	No
Quanta PHOS®	439030	ACP, NPAP	+2°C to +8°C	20 days	No
SYNCHRON® Control Levels 1, 2, 3	657365	Multianalyte	+2°C to +8°C	20 days	No
Ultimate® -D Control					
Level 1	667710	DBIL, TBIL	+2°C to +8°C	7 days	No
Level 2	667720	DBIL, TBIL			
Level 3	667730	DBIL, TBIL			
Level 4	667740	DBIL, TBIL			
Urine Protein Control					
Level 1	465290	MA	+2°C to +8°C	Expiration date	No
Level 2	465300	MA			
Vigil™ HbA1c Control					
Level 1, 2	650038	HB, A1C	+2°C to +8°C +20° to +25°C -15°C to -25°C	1 week 8 hours 3 months	Yes
Vigil™ Lipid Control					
Level 1	469905	CHOL, HDLC, HDLD, LDLD, TG, TG-B	+2°C to +8°C	60 days	No
Level 2	465980	CHOL, HDLC, HDLD, LDLD, TG, TG-B			
Level 3	465981	CHOL, HDLC, TG, TG-B			
Level 4	465982	CHOL, HDLC, HDLD, LDLD, TG, TG-B			
Vigil™ Protein Control					
Level 1	450120	ALB, TP, IGG, IGM, IGA, PAB, TRF	+2°C to +8°C	60 days	No
Level 2	450125	ALB, TP, IGG, IGM, IGA, PAB, TRF			
Level 3	450130	ALB, TP, IGG, IGM, IGA, PAB, TRF			

Table 43.0 Controls, Continued

Control	Part Number	Use	Open Bottle Storage Temp.	Open Bottle Stability	Prep?
Vigil™ Serology Control Level 1 Level 2 Level 3	 450162 450163 450164	 CRP, C-RP, ASO-, RF CRP, C-RP, ASO-, RF CRP, C-RP, ASO-, RF	+2°C to +8°C	60 days	No
Vigil™ TDM Control Level 1 Level 2 Level 3	 472461 472467 472472	 ACTM, CAR, DIGN, GEN, PHE, PHY, SALY, THE, TOB, VPA ACTM, CAR, DIGN, GEN, PHE, PHY, SALY, THE, TOB, VPA ACTM, CAR, DIGN, GEN, PHE, PHY, SALY, THE, TOB, VPA	+2°C to +8°C	Expiration date	No

Table 44.0 Solutions

Solution	Part Number	Use	Open Bottle Storage Temp.	Open Bottle Stability	Prep?
Antifoam	445967	Creatinine reagent additive	Room Temperature	Expiration date	No
DIL1 (CX® PRO Systems only)	467826	Serum Index, On-board dilution (immunoproteins, urines)	Room Temperature	60 days	No
Probe Rinse +	476015	Internal probe cleaner	Room Temperature	Expiration date	Yes
Trace-Klean	589784	Maintenance of probes and mixers	Room Temperature	Expiration date	Yes
Wash Concentrate II	450160 445865	Wash cuvettes, rinse probes/mixers	Room Temperature	Expiration date	No
Wash Concentrate Solution (CX3)	443335	Diluent for some reagents and a cleaning solution for some components	Room Temperature	Expiration date	Yes
SYNCHRON Systems Hemolyzing Reagent	472137	Diluent for HbA1C sample preparation For use as A1C Level 1 Calibrator	+2°C to +8°C	Expiration date	No

SYNCHRON CX® PRO System Serum Index

PRINCIPLE

INTENDED USE

The serum index function, in conjunction with a SYNCHRON Systems DIL1 reagent, is intended for the semi-quantitative determination of a sample condition. This is determined in terms of icterus (bilirubin), hemolysis (hemoglobin), and lipemia in serum or plasma on SYNCHRON CX PRO Systems. Serum index is not intended to be used to diagnose a patient, but to indicate the condition of a test sample.

CLINICAL SIGNIFICANCE

Bilirubin, hemoglobin, and/or lipemia may act as an interferent depending upon an analyte being measured. Refer to individual chemistry information sheets for more information on interferences affecting specific analytes.

METHODOLOGY

DIL1 buffer is used to measure the serum indices by a spectrophotometric method.

A precise volume of sample (14 µL) is injected in a cuvette containing 200 µL of buffer. The ratio used is one part sample to 14.3 parts reagent. The system monitors the absorbance at 340, 410, 470, 600 and 670 nm and solves a set of equations to determine the response for each index. The response is directly proportional to the sample condition in terms of icterus (bilirubin), hemolysis (hemoglobin), and lipemia.

SPECIMEN

Biological fluid samples should be collected in the same manner routinely used for any laboratory test. Freshly drawn serum or plasma are the preferred specimens.

- Refer to individual chemistry information sheets for information on specimen requirements affecting specific analytes.
- Treated samples (e.g., after reagent treatment and centrifugation or column preparation) do not represent the original specimen condition for serum index.

REAGENT REQUIRED

SYNCHRON Systems DIL1

Kit Reorder #467826

CONTENTS

Each kit contains the following items:

Two cartridges of DIL1

Note: The number of tests available varies depending on the number of urine samples, serum index and immunoprotein assays in proportion to the total samples processed.

VOLUMES PER TEST

Sample Volume: 14 µL

Reagent Volume: 200 µL

REAGENT PREPARATION

No preparation is required.

STORAGE AND STABILITY

DIL1 stored unopened at room temperature is stable until the expiration date indicated on each cartridge. Once opened, DIL1 is stable for 60 days on instrument or until the expiration date, if sooner.

SYSTEM INFORMATION

CALIBRATION

Calibration is not required.

TESTING PROCEDURE

1. If necessary, load the reagent onto the system as directed in the *Quick Reference Guide* at the beginning of this manual or refer to the SYNCHRON CX *Operating Instructions* manual.
2. With the serum index function enabled, program samples for analysis as directed in the *Quick Reference Guide* or refer to the SYNCHRON CX *Operating Instructions* manual.
3. After loading samples onto the system, follow the protocols for system operation as directed in the *Quick Reference Guide* or refer to the SYNCHRON CX *Operating Instructions* manual.

LIMITATIONS

1. Sulfasalazine interferes with this methodology. Samples containing sulfasalazine should not be used.
2. The integrity of all indices should be verified if any of the indices are suppressed OIR HI.
3. Results for samples containing rare IgM immunocomplexes may be suppressed with RX RATE HI and INIT RATE HI messages.
4. Fluorescein interferes with this methodology. Samples containing fluorescein should not be used.

BILIRUBIN INDEX INTERFERENCES

The following substances were tested for interference with the bilirubin index:

Table 45.0 Bilirubin Index Interferences

Substances	Source	Level Tested	Observed Effect
Hemoglobin	RBC Hemolysate	500 mg/dL	NSI[a]
Lipemia	Intralipid[b]	400 mg/dL	NSI

a NSI = No Significant Interference (within ± 1 unit).
b Intralipid is a registered trademark of KabiVitrum, Inc.

HEMOGLOBIN INDEX INTERFERENCES

The following substances were tested for interferences with the hemoglobin index:

Table 46.0 Hemoglobin Index Interferences

Substances	Source	Level Tested	Observed Effect
Bilirubin	Human	30 mg/dL	NSI[a]
Lipemia	Human	400 mg/dL	NSI

a NSI = No Significant Interference.

LIPEMIA INDEX INTERFERENCES

The following substances were tested for interference with the lipemia index:

Table 47.0 Lipemia Index Interferences

Substances	Source	Level Tested	Observed Effect
Bilirubin	Human	30 mg/dL	NSI[a]
Hemoglobin	RBC Hemolysate	500 mg/dL	NSI

a NSI = No Significant Interference.

Serum Index Tables

INTRODUCTION

Beckman Coulter has established the following serum index tables. Once the system has determined the level of a specific interferent, it is applied to the table to derive the appropriate index value.

BILIRUBIN INDEX

The following table contains bilirubin index data.

Table 48.0 Bilirubin Index Data

Icteric Index Level	Approximate Bilirubin Range (mg/dL)	Approximate Bilirubin Range (µmol/L)
0	None detected	None detected
1	0.0 to 1.5	0.0 to 25.7
2	1.5 to 3.0	25.7 to 51.3
3	3.0 to 4.5	51.3 to 77.0
4	4.5 to 6.0	77.0 to 102.6
5	6.0 to 7.5	102.6 to 128.3
6	7.5 to 9.0	128.3 to 153.9
7	9.0 to 10.5	153.9 to 179.6
8	10.5 to 12.0	179.6 to 205.2
9	12.0 to 13.5	205.2 to 230.9
10	13.5 to 15.0	230.9 to 256.5
11	15.0 to 16.5	256.5 to 282.2
12	16.5 to 18.0	282.2 to 307.8
13	18.0 to 19.5	307.8 to 333.5
14	19.5 to 21.0	333.5 to 359.1
15	21.0 to 22.5	359.1 to 384.8
16	22.5 to 24.0	384.8 to 410.4
17	24.0 to 25.5	410.4 to 436.1
18	25.5 to 27.0	436.1 to 461.7
19	27.0 to 28.5	461.7 to 487.4
20	28.5 to 30.0	487.4 to 513.0

HEMOGLOBIN INDEX

The following table contains hemoglobin index data.

Table 49.0 Hemoglobin Index Data

Hemolysis Index Level	Approximate Hemoglobin Range (mg/dL)	Approximate Hemoglobin Range (g/L)
0	None detected	None detected
1	0 to 50	0.0 to 0.5
2	50 to 100	0.5 to 1.0
3	100 to 150	1.0 to 1.5
4	150 to 200	1.5 to 2.0
5	200 to 250	2.0 to 2.5
6	250 to 300	2.5 to 3.0
7	300 to 350	3.0 to 3.5
8	350 to 400	3.5 to 4.0
9	400 to 450	4.0 to 4.5
10	450 to 500	4.5 to 5.0

LIPEMIA INDEX

The following table contains lipemia index data.

Table 50.0 Lipemia Index Data

Lipemia Index Level	Visual Turbidity Level (Beckman Coulter Scale)	Approximate Range (Intralipid[a] mg/dL)
0	None detected	None detected
1	0	0 to 40
2	1+	40 to 80
3	2+	80 to 120
4	2+	120 to 160
5	2+	160 to 200
6	3+	200 to 240
7	3+	240 to 280
8	3+	280 to 320
9	4+	320 to 360
10	4+	360 to 400

a Intralipid is a registered trademark of KabiVitrum, Inc.

APPENDIX A Lipemia Chart

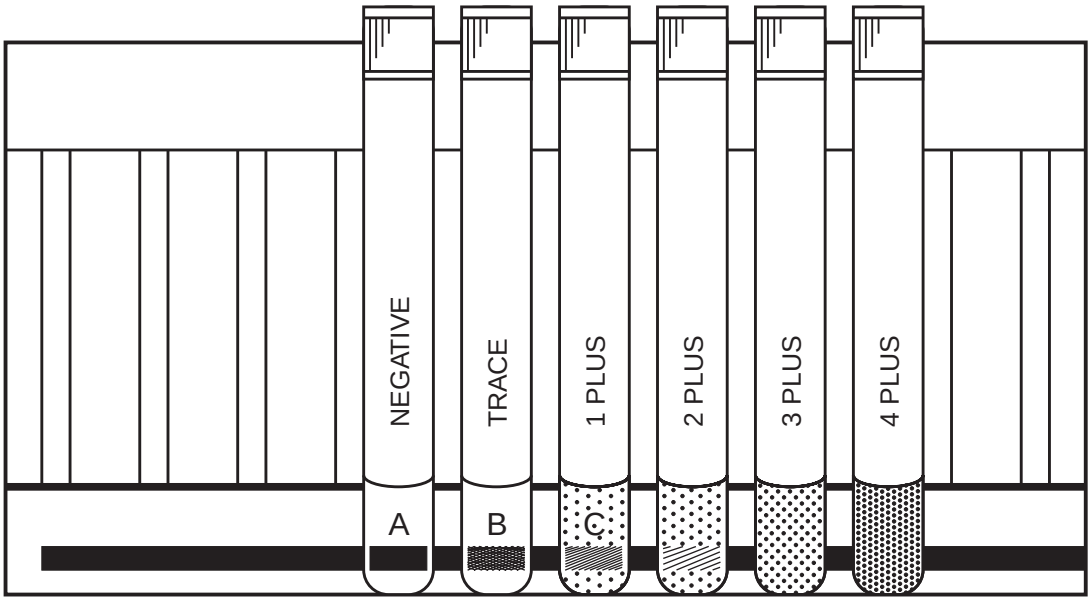

Figure 1.0 Lipemia Chart